

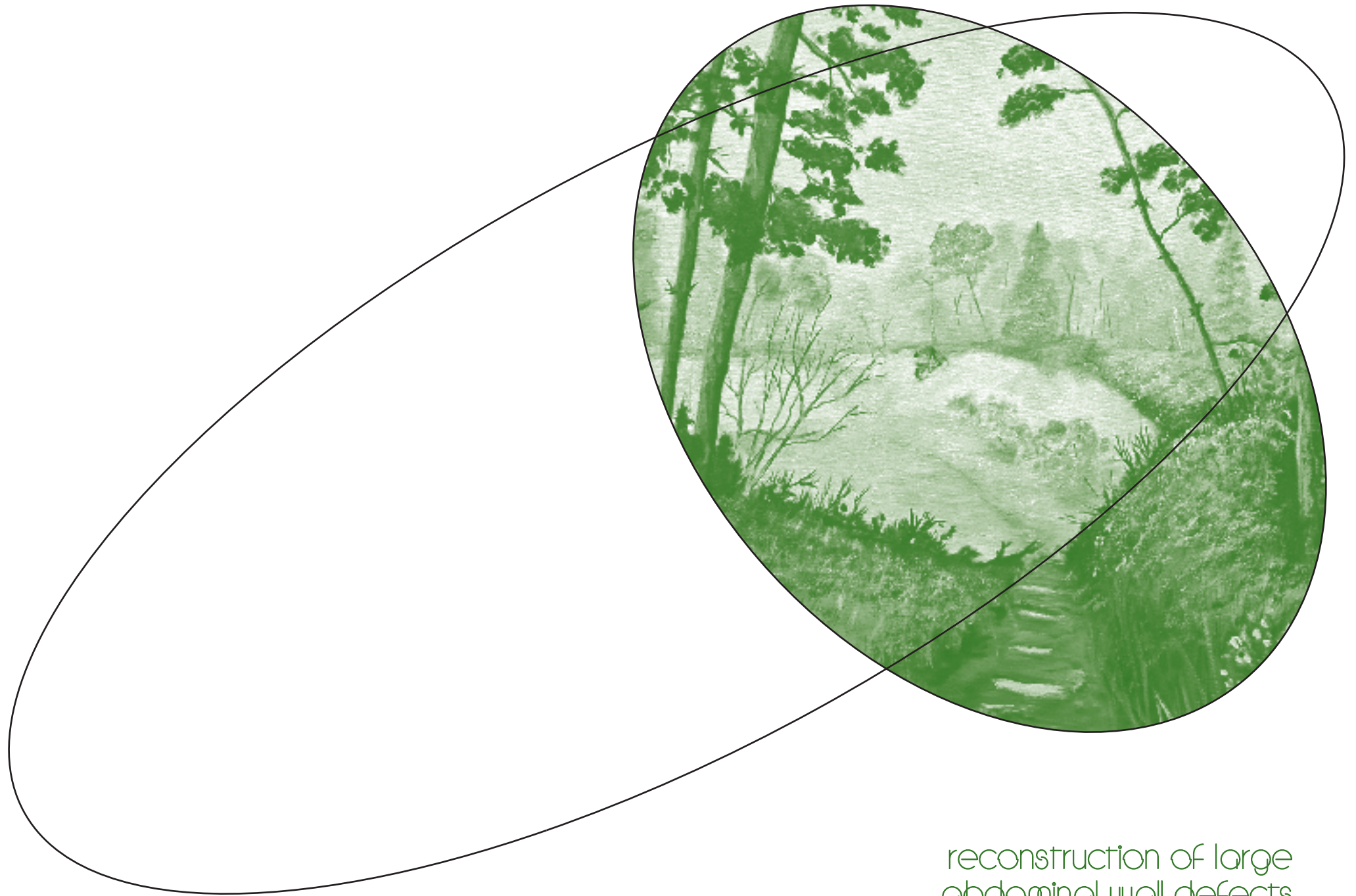
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reconstruction of large  
abdominal wall defects

‘components separation technique’ and prosthetic repair

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# Reconstruction of large abdominal wall defects

## “Components Separation Technique” and Prosthetic Repair

een wetenschappelijke proeve  
op het gebied van de Medische Wetenschappen

## Proefschrift

ter verkrijging van de graad van doctor  
aan de Radboud Universiteit Nijmegen  
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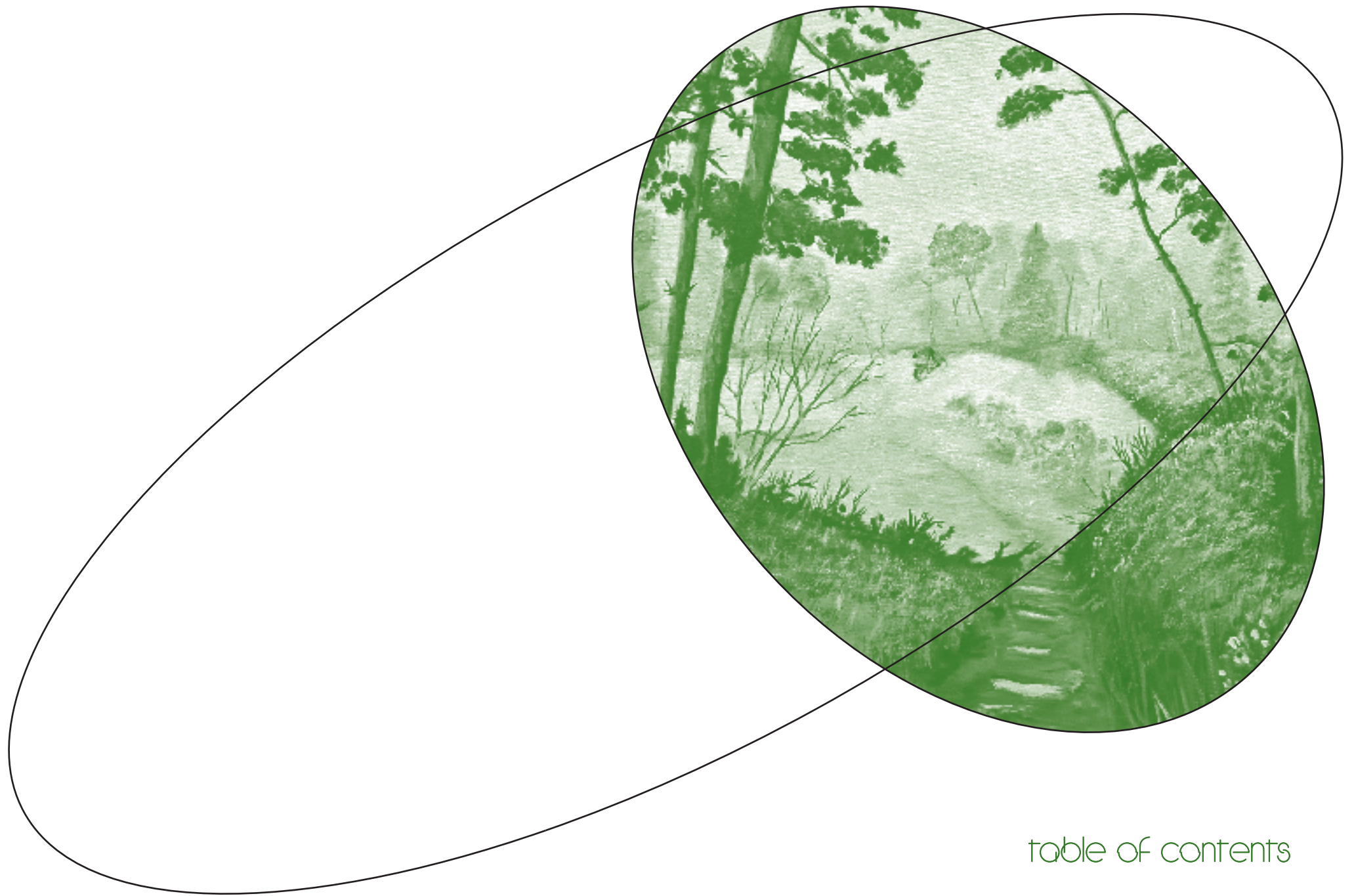
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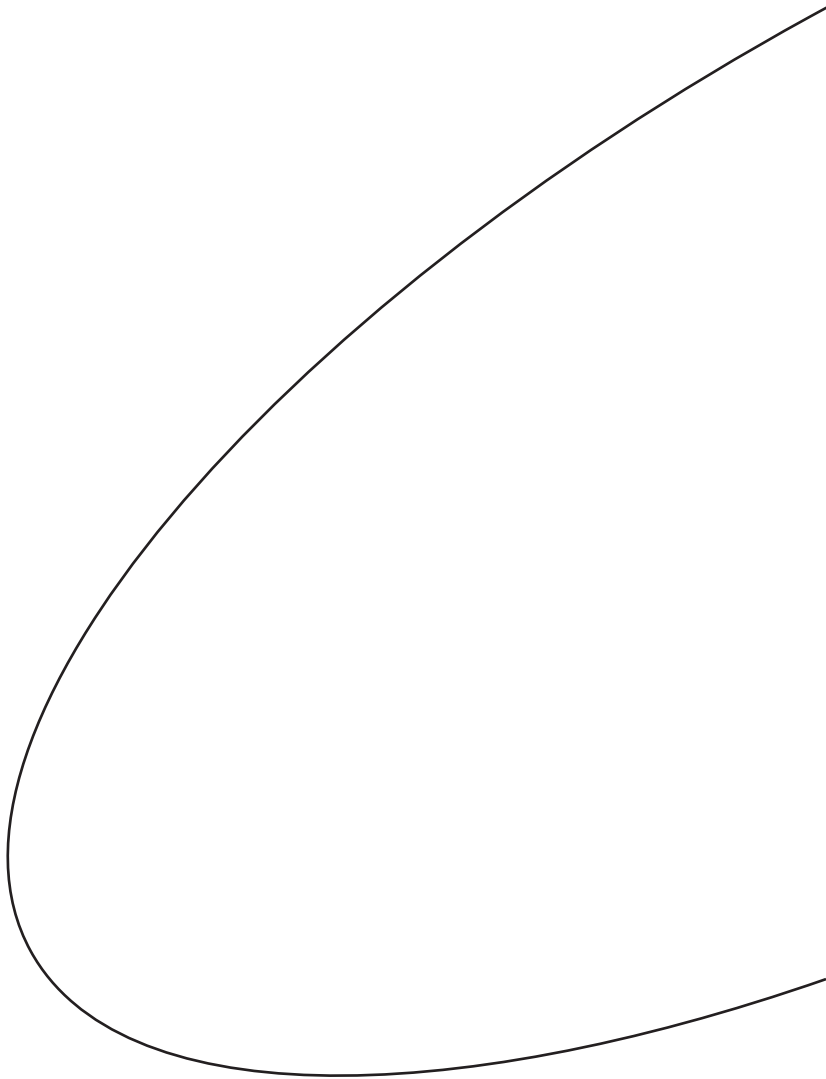
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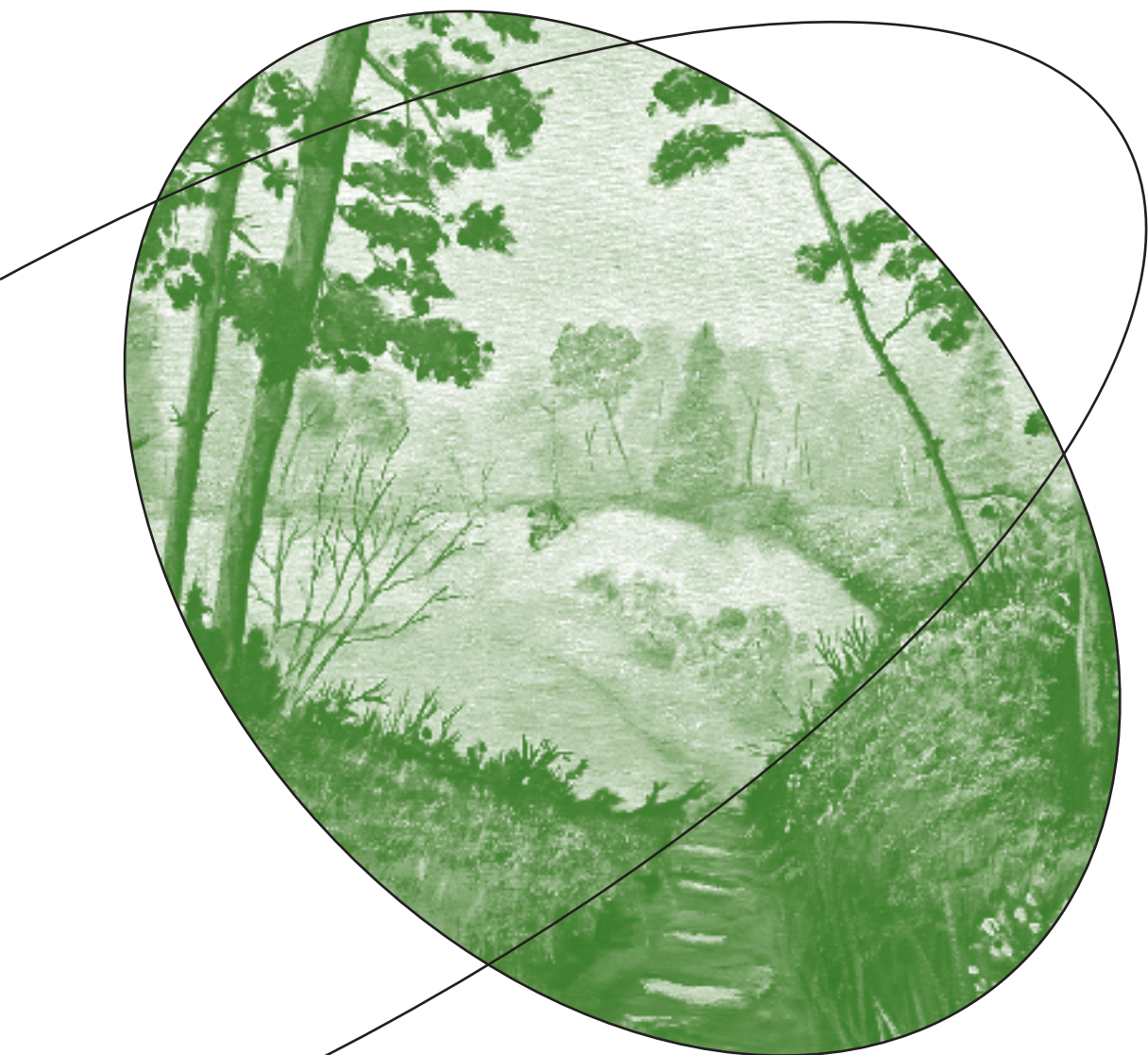
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prologue



An incisional hernia is a protrusion of the peritoneum through a defect in a scar in the abdominal wall fascia. After laparotomy, about 10% of the patients develop an incisional hernia.<sup>1-4</sup> The risk after midline laparotomies is greater than after transverse incisions.<sup>5</sup> Several techniques have been described to repair incisional hernias. Principally three methods can be discriminated: (I) primary closure of the fascia (suture repair), (II) prosthetic repair, to re-inforce primary closure or to bridge fascial defects and (III) repair with autologous tissue to bridge the fascial gap, either by local tissue transfer or free grafts, pedicled or free-vascularised tissue flaps.

Suture repair is the most simple technique, resulting in more than 50% recurrent hernias.<sup>3,6,7</sup> Prosthetic repair gives favourable results as is concluded from numerous, mostly retrospective studies, reporting recurrence rates of less than 10%, as reviewed by Cassar and Munro.<sup>8</sup> However, in two prospective randomized trials, recurrence rates of 7 to 32% are reported, after a follow-up of 2 to 10 years.<sup>6,7,9</sup> Autologous repair is mostly used in patients with large and complex abdominal wall defects.

The present thesis focuses on midline abdominal wall hernias or defects that cannot be closed primarily, often resulting from intra-abdominal catastrophes or recurrent incisional hernias. In these hernias, the large fascial gap results from retraction of the rectus abdominis muscle, prohibiting tension free primary closure of the fascia. In a considerable part of patients, these “defects” are accompanied by contamination or infection.

The usual technique to repair large hernias is to bridge the fascial gap by prosthetic material. This technique has several disadvantages. First, the use of prosthetic material increases the risk of infection. Second, the prosthetic material may erode into the skin or bowels, often resulting in prosthetic loss.<sup>10</sup> Third, prosthetic repair results in a less dynamic support of the abdominal wall and sometimes in less favourable cosmetic results due to bulging of the prosthesis. Moreover, prosthetic material is contraindicated in the presence of contamination or infection.

Until now, the ideal prosthetic material for abdominal wall repair is not available. In very large hernias, where the peritoneum and/or the greater omentum are often lacking, dense adhesions to the bowels or damage to the intra-abdominal viscera may occur when polypropylene is used.<sup>11,12, 13</sup> The ideal prosthesis combines two conflicting properties: (I) incorporation of the mesh into the fibrocollagenous tissue for adequate

anchorage to the adjacent fascia and (II) no adhesions to the mesh. Moreover, prosthetic repair increases the risk of infection, which is a major risk in patients with large hernias since wound complications are frequent.

Autologous repair may overcome the abovementioned drawbacks. However, donor-site morbidity, wound healing disturbances and relatively high reherniation rates are limiting factors for its application, as reviewed by de Vries Reilingh et al. (Chapter 3).<sup>14</sup> The most often used method for autologous repair is the “components separation technique” described by Ramirez.<sup>15</sup>

## objectives

The first objective of this thesis was to assess outcomes of the “components separation technique” and to investigate modification of the technique for improvement.

The second objective of this thesis was to study various prosthetic materials, including impregnated and composed meshes, with focus on reherniation, infection prevention, wound healing disturbances and adhesion formation.

## outline

### Part 1

**Part 1** of the thesis is dedicated to the “components separation technique” (CST) first described by Ramirez, Ruas and Dellon in 1990.<sup>15</sup> **Chapter 1** describes the anatomy of the abdominal wall and the “components separation technique”. In **Chapter 2** the results of a retrospective study, evaluating CST in five hospitals in The Netherlands, are reported. **Chapter 3** reviews abdominal wall repair with autologous material including CST, da Silva technique, reconstruction with fascia lata and dermal grafts, and pedicled or free vascularized musculo-cutaneous flaps. **Chapter 4** presents the results of a randomized controlled trial comparing CST with prosthetic repair. In **Chapter 5** the results of a minimal invasive technique to perform CST are described.

### Part 2

In **Chapter 6** the optimal position for placement of a polypropylene mesh in hernia repair is studied. In chapter 7, 8, and 9, three experimental studies optimizing prosthetic material for abdominal wall repair are presented. In **Chapter 7** the effect of silver salts and chlorhexidine impregnation of e-PTFE patches on biocompatibility, adhesion formation and reherniation is described. In **Chapter 8** prevention of adhesions formation between polypropylene mesh and the bowels by interposition of polyglactin 910 mesh was studied. In **Chapter 9** several other mechanical and chemical barriers are studied, to prevent adhesion formation to a polypropylene mesh.

### Part 3

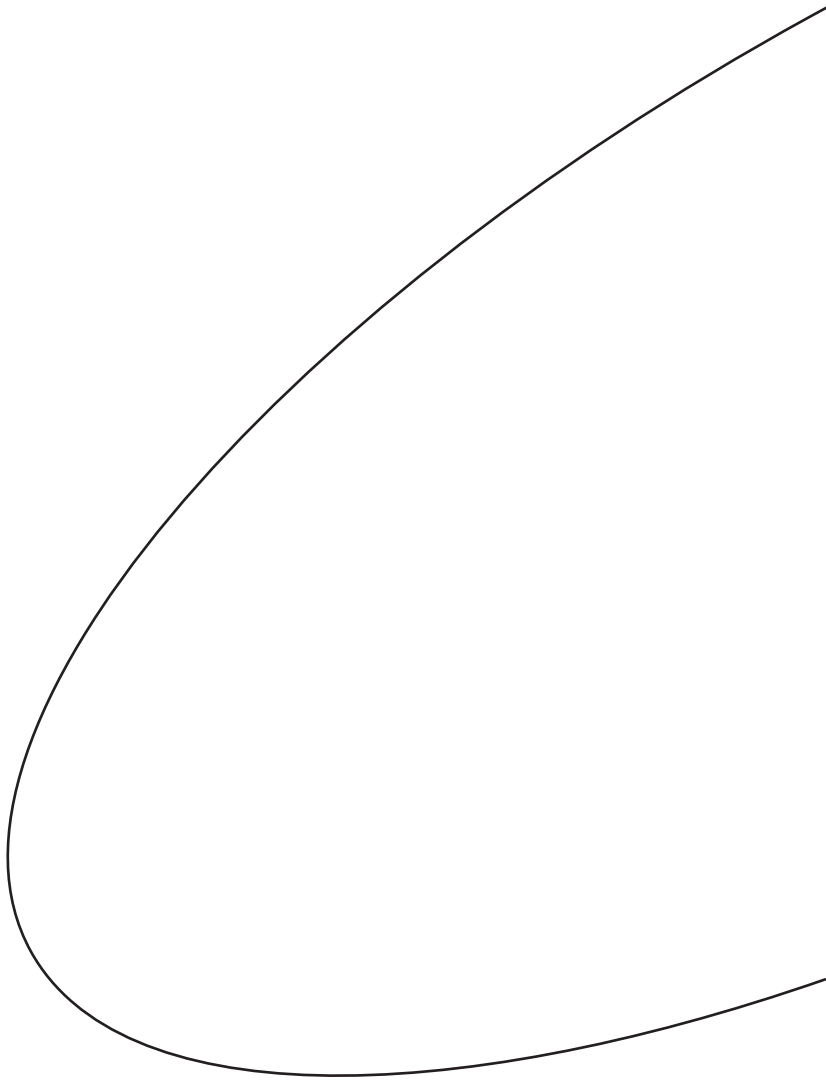
**Chapter 10** summarizes the thesis, contains a general discussion and recommendations are outlined.

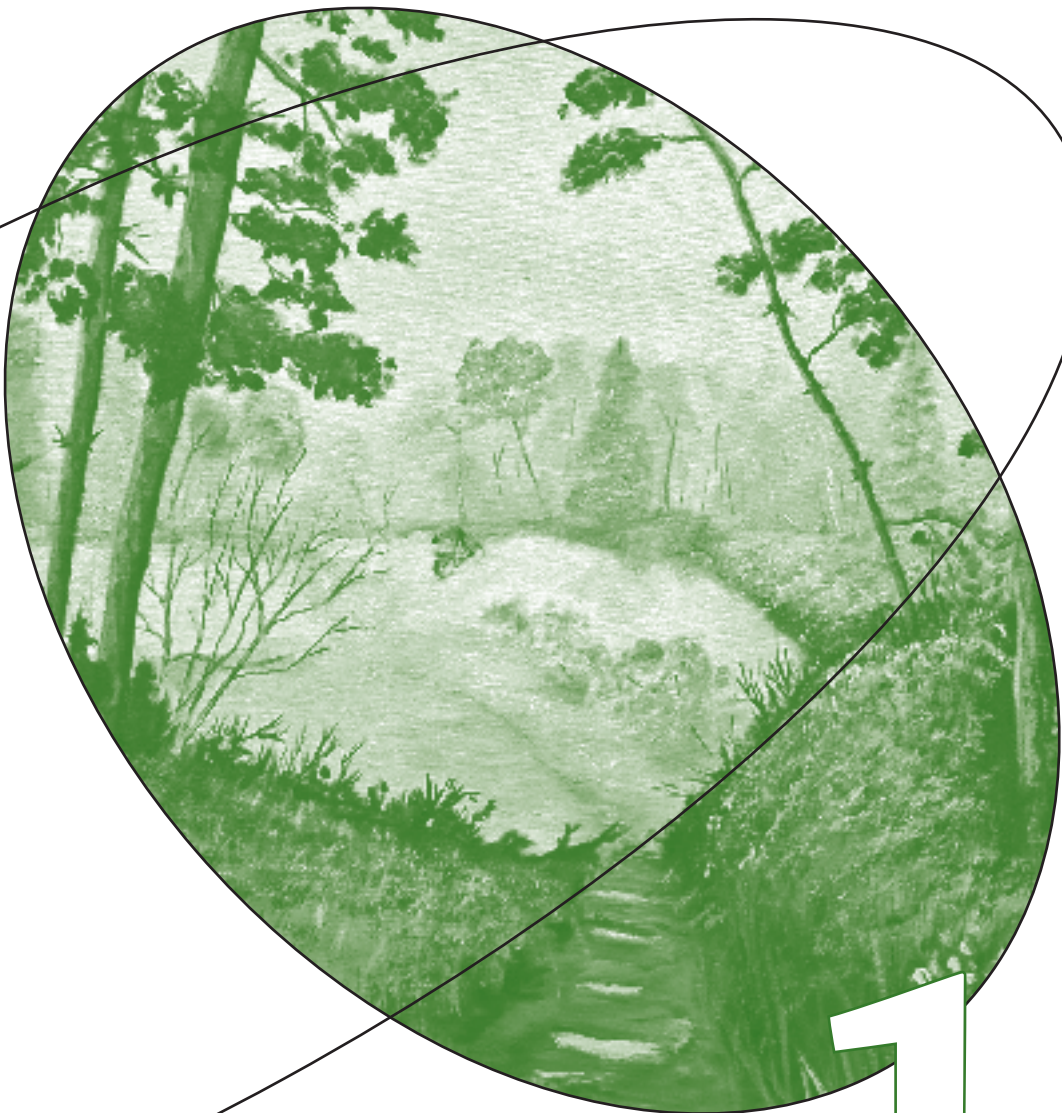
**Chapter 11** contains a Dutch summary, general discussion and recommendations.

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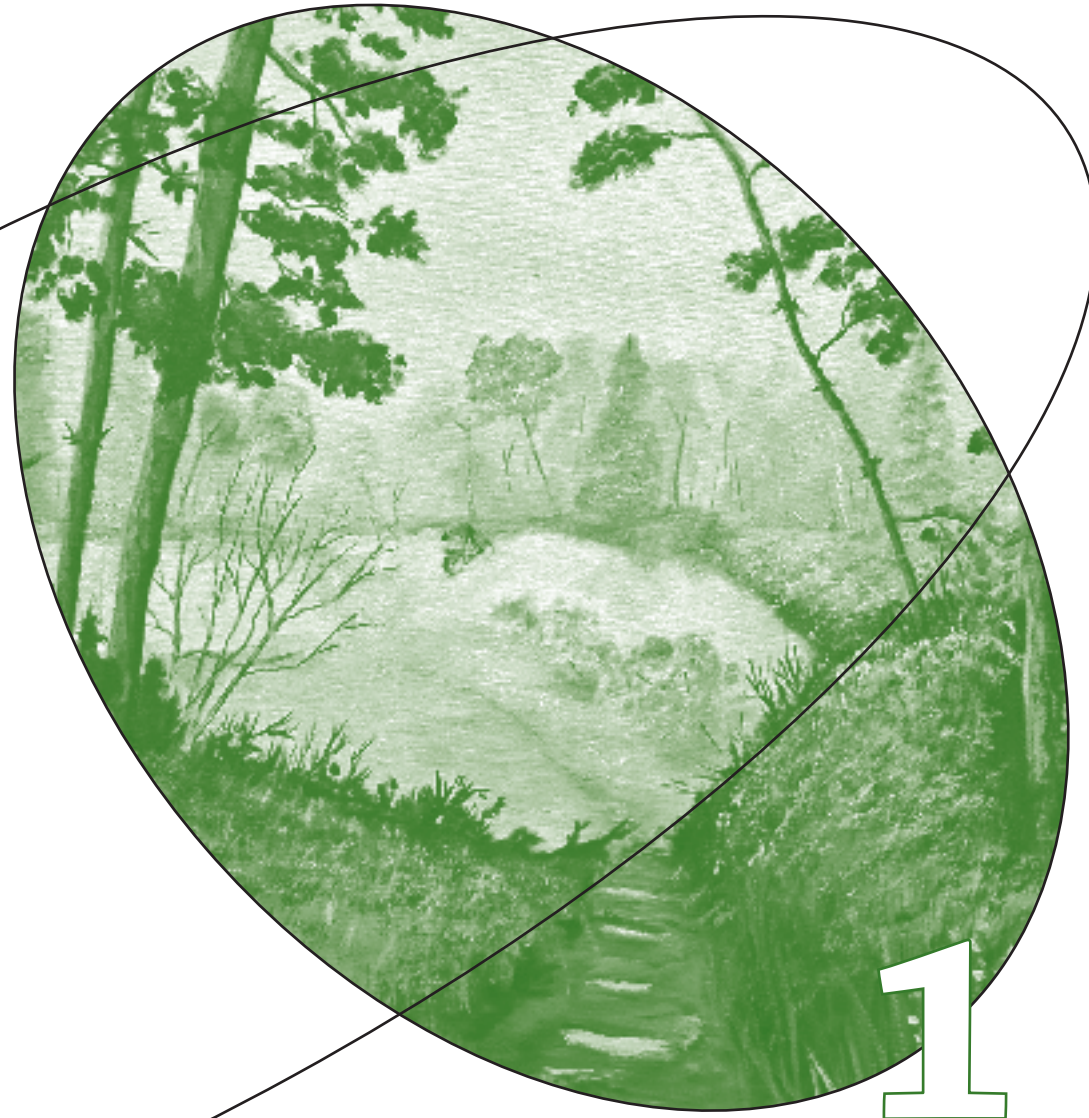
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part 1





## “components separation technique” to repair large midline hernias

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*Operative Techniques in General Surgery* 2004; 6(3):179-188



## introduction

Reconstruction of large, midline abdominal wall hernias that cannot be closed primarily is a major problem. Several techniques have been advocated to repair these defects. Reconstructions with autologous material, such as free human dermis and free fascial or musculo-fascial flaps, is unsatisfactory.<sup>1,2</sup> Free human dermis is too weak to resist the intra-abdominal pressure over time, and harvesting of (free) fascial transplants is time-consuming and frequently followed by functional deficits at the donor site. The functional results of reconstructions with vascularized composite grafts are often disappointing because of bulging of the denervated muscles, with recurrence rates up to 20%.<sup>2</sup> Local techniques for reconstruction with the sheaths of the rectus abdominis muscle gives disappointing results as well.<sup>3</sup> Currently, bridging the defect with a biomaterial is the preferred treatment. Polypropylene mesh is the most widely used biomaterial. However, contact between the mesh and intra-abdominal viscera must be prevented by interposition of the peritoneum or greater omentum. Moreover, full-thickness skin coverage of the mesh is essential, and its use is contraindicated in the presence of contamination or infection.<sup>2,4,5</sup>

In 1990, Ramirez et al<sup>6</sup> developed a technique for reconstructing abdominal wall defects without the use of prosthetic material. The technique is based on enlargement of the abdominal wall surface by translation of the muscular layers without severing the innervation and blood supply of the muscles. We modified the technique for the patient with enterostomies and developed a minimally invasive technique to diminish the wound surface.<sup>7,8</sup>

## anatomy of the ventral abdominal wall

The skin and subcutaneous tissue cover the muscles of the ventral abdominal wall. The arterial blood supply of the skin comes mainly from the intercostal arteries and the perforating branches of the epigastric artery. The muscles of the ventro-lateral abdominal wall are the external oblique, internal oblique, and transversus abdominis, which insert into the anterior and posterior sheaths of the rectus abdominis muscle (Figure 1 and 2).

### Muscles (Figure 1)

The rectus abdominis muscle (a) originates from the lower anterior wall of the thorax and inserts on the pubic bone. It is enveloped by the anterior and posterior rectus sheath, formed out of the aponeurosis of the lateral abdominal muscles, which fuse in the midline at the linea alba (b). The posterior rectus sheath is absent below the semilunar line.

The external oblique muscle (c,d) originates from the thoracic wall and the iliac crest and runs in a caudal direction forward. The cranial part extends a considerable distance above the costal margin. The aponeurosis of the external oblique muscle forms the anterior rectal sheath and ends caudally as the Poupart ligament (e). The internal oblique muscle inserts (f) on the pelvic skeleton and runs cranially forward, cross-

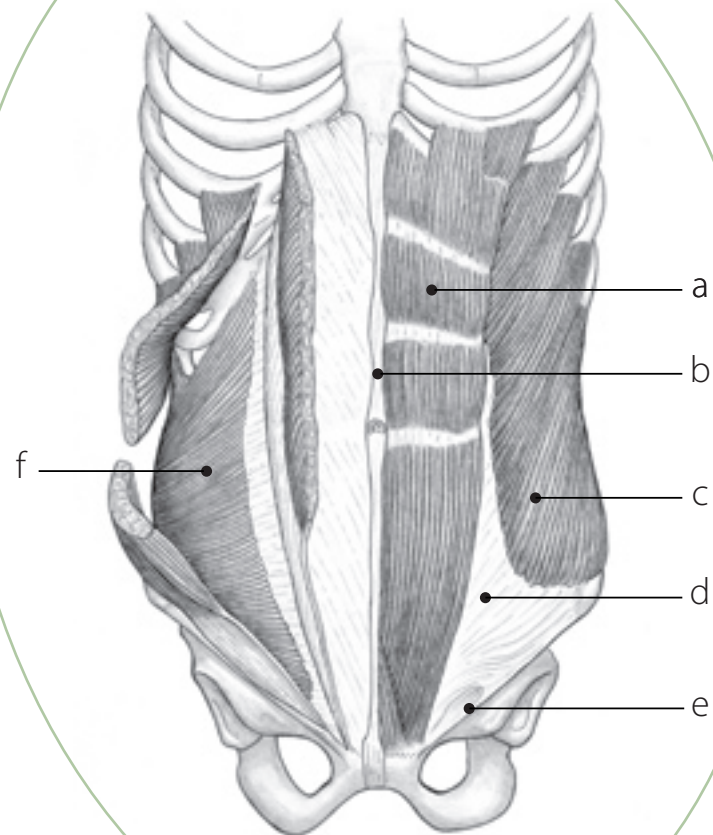


Figure 1

*Anatomy of the ventral abdominal wall.*

ing the fibers of the external oblique muscle. The aponeurosis of the internal oblique muscle splits into an anterior and posterior part. The anterior part forms the anterior layer of the rectus sheath, together with the external oblique muscle. The posterior part fuses with transversus abdominis, forming the posterior rectus sheath, superior to the linea semilunaris. The internal oblique muscle is firmly attached to the costal margin. The transversus abdominis muscle originates from the posterior aspects of the 6th to 12th ribs, the lumbodorsal fascia, the iliac crest, and iliopsoas fascia and runs horizontally to the rectus abdominis sheath.

### Innervation (Figure 2)

The muscles of the anterolateral ventral abdominal wall are innervated by the 7th to 12th intercostal nerves and the iliohypogastric and ilioinguinal nerves. The nerves (a) run together with the accompanying arteries and veins between the internal oblique (b) and the transversus abdominis muscle (f) forward, and branches are given to each muscle and the overlying skin (d). The segmental neurovascular bundles penetrate the internal oblique contribution to the posterior rectus sheath at the postero-lateral side to supply the rectus muscle (g) and the overlying skin, close to the axis of the epigastric arteries, about 10 to 25 mm medially from the lateral border of the rectus sheath (e).<sup>2</sup>

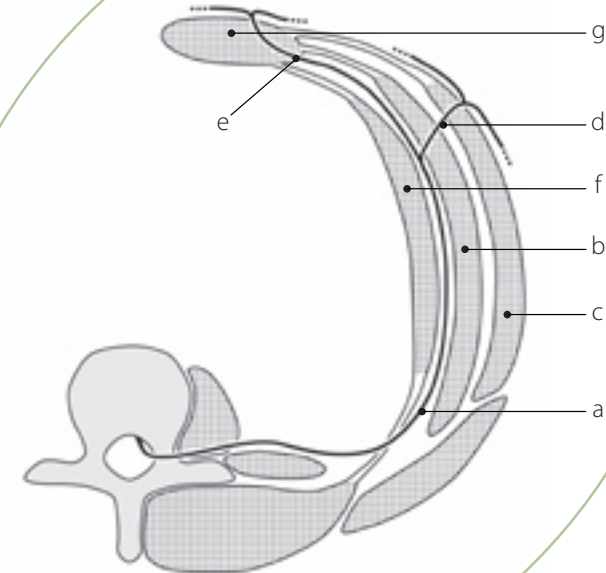


Figure 2

*The neurovascular bundle in relation to the abdominal wall vasculature.*

### Blood Supply (Figure 3)

The blood supply of the ventral abdominal wall comes mainly from the epigastric and intercostal arteries. The skin of the ventral abdominal wall is supplied by the periumbilical musculocutaneous perforators (a) of the superior (b) and inferior (c) epigastric arteries and the intercostal arteries (d) but also by branches of the superficial epigastric artery and the superficial circumflex iliac and external pudendal arteries (c).

The blood supply of the muscular layers of the abdominal wall comes from the superior (e) and inferior (f) epigastric arteries, together with the intercostal arteries (g).

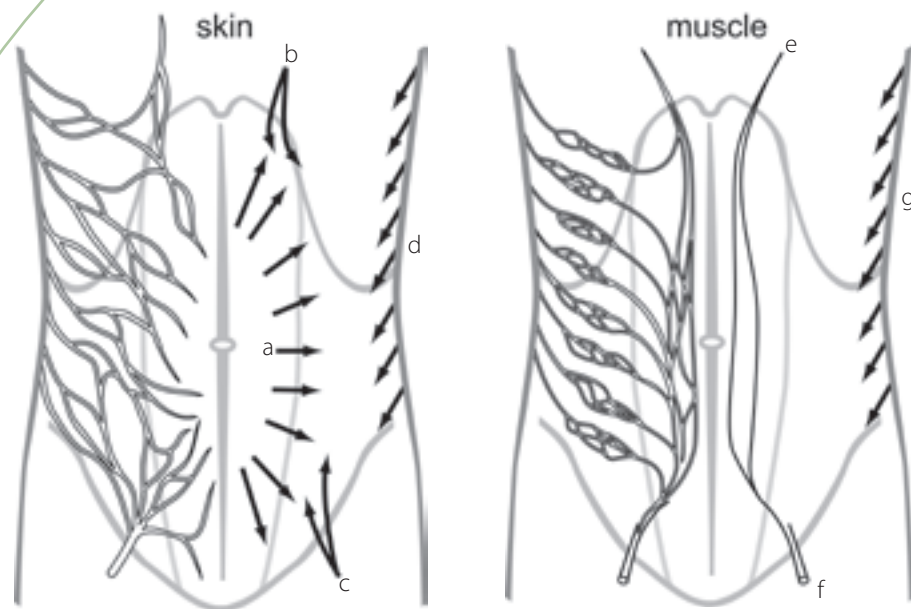


Figure 3

*Blood supply of the skin and muscles of the ventral abdominal wall.  
(Adapted from Taylor et al.<sup>9</sup>)*

### Preoperative care

A combination of epidural and general anesthesia is administered. Antibiotics are started before the operation because the procedure often takes more than 3 hours, large wound surfaces are created, iatrogenic bowel perforation may occur, and on occasion biomaterials are used.

### Operative technique

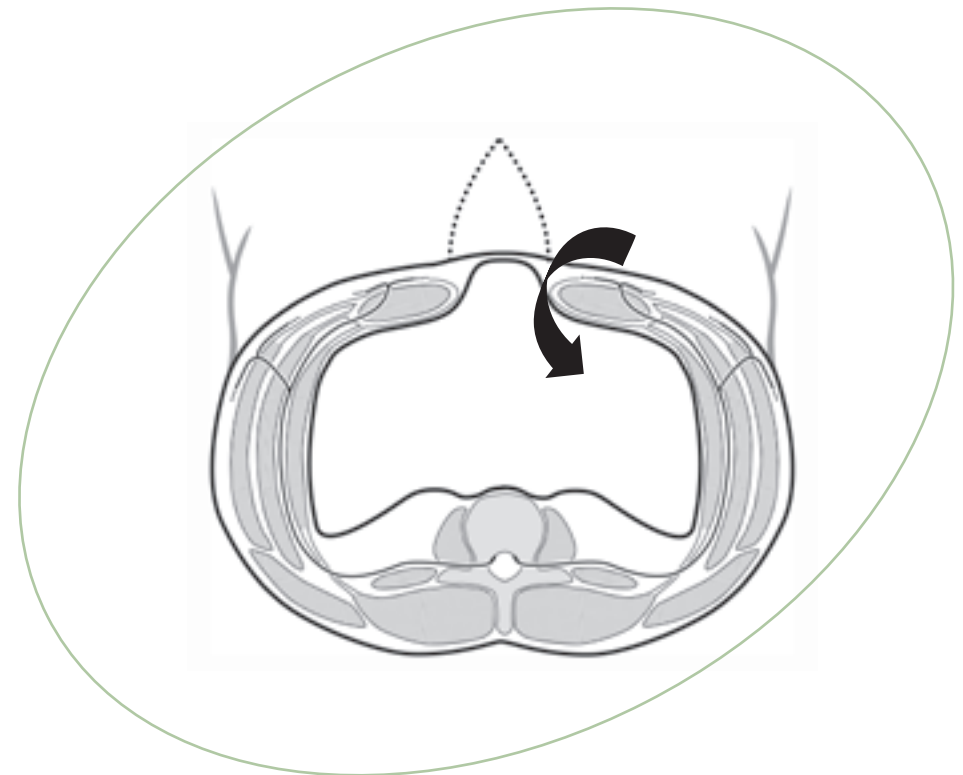
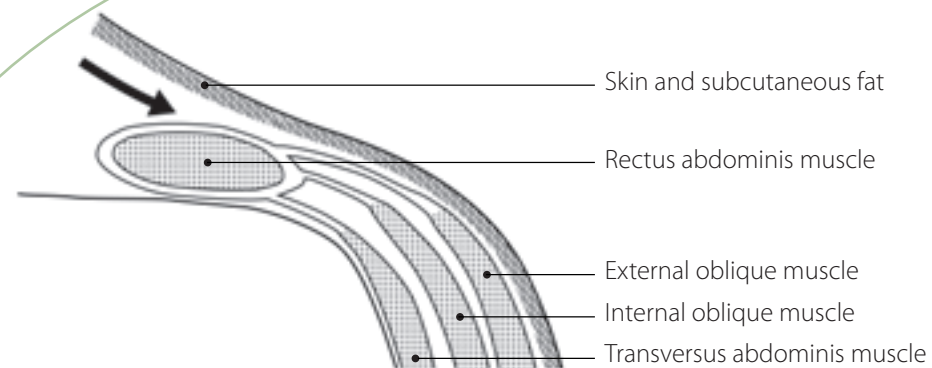
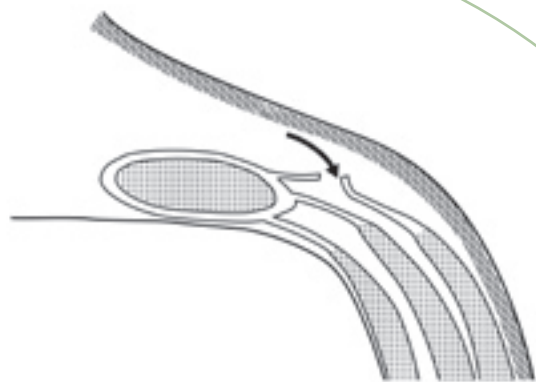


Figure 4

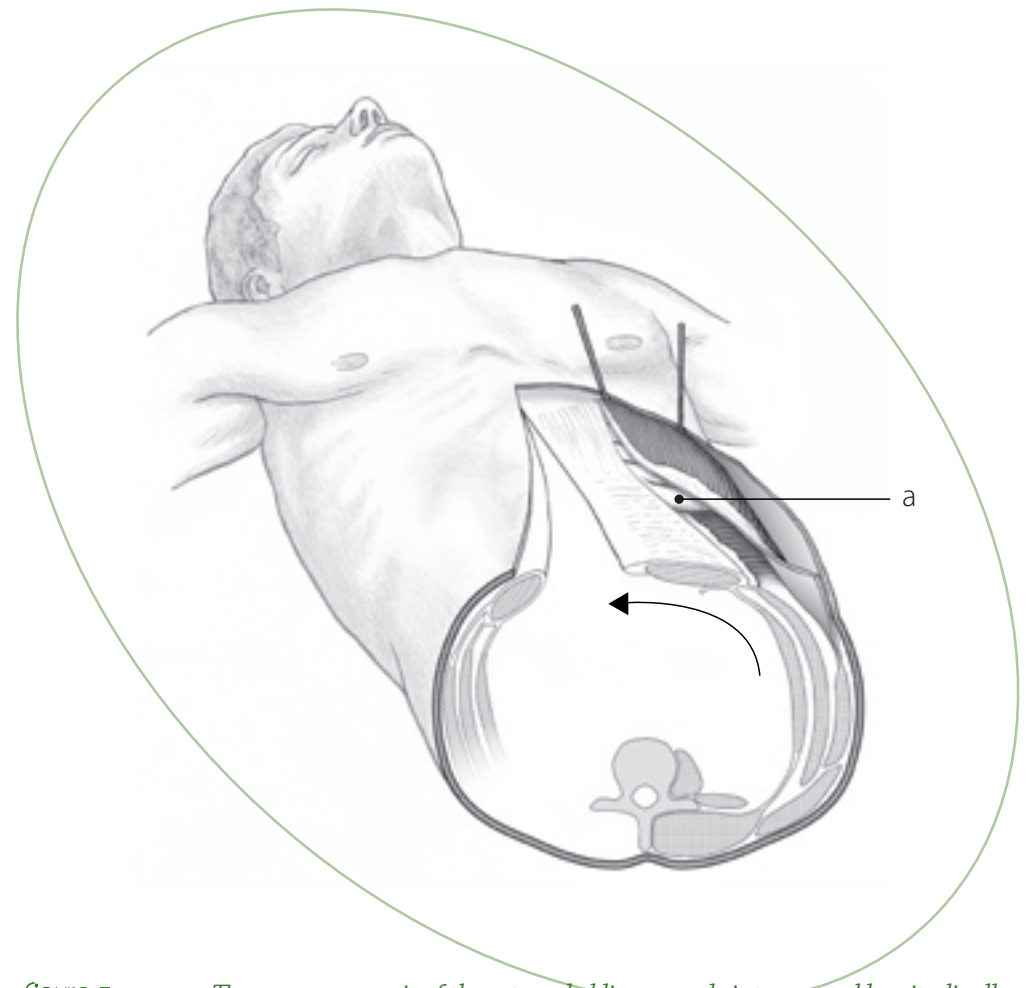
*The patient is placed in a supine position. The skin is opened via a midline incision. If a skin defect exists or if the intestine is covered with a split-thickness skin graft, the abdominal cavity is entered via an incision just lateral to the defect. The intestine and other viscera are dissected free from the ventral abdominal wall. By doing this, the lateral border of the rectus abdominal muscle can be identified properly from the inside of the abdomen.*



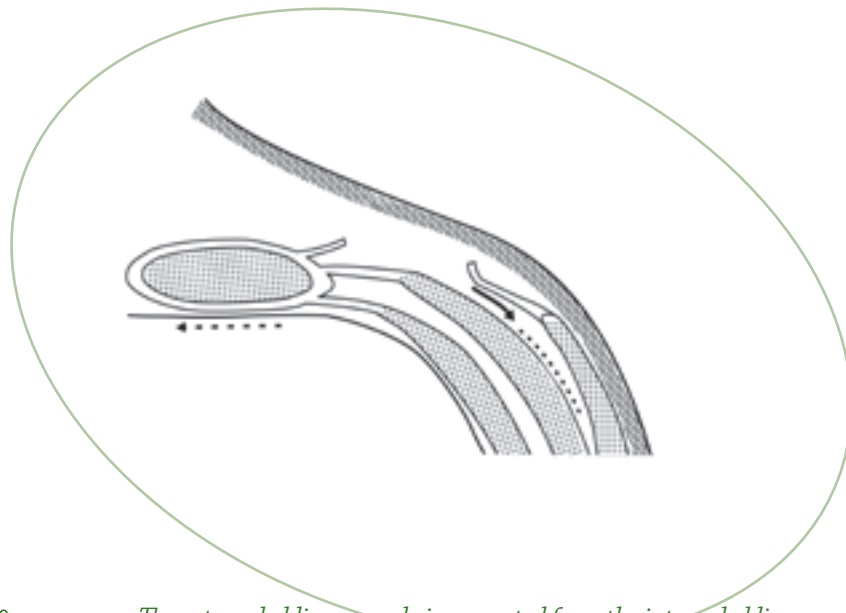
**Figure 5** The skin and subcutaneous fat are dissected free from the anterior rectus sheath and the aponeurosis of the external oblique muscle to about 5 cm lateral to the lateral border of the rectus sheath. Because the perforating branches of the epigastric artery are transected, the blood supply of the skin is at risk, since it then solely depends on the intercostal arteries and branches of the pudendal artery. This is of utmost importance for patients in whom the intercostal vessels are not intact as a result of previous surgery, eg, subcostal incision or stoma placement. In these cases, the epigastric perforators must be spared.



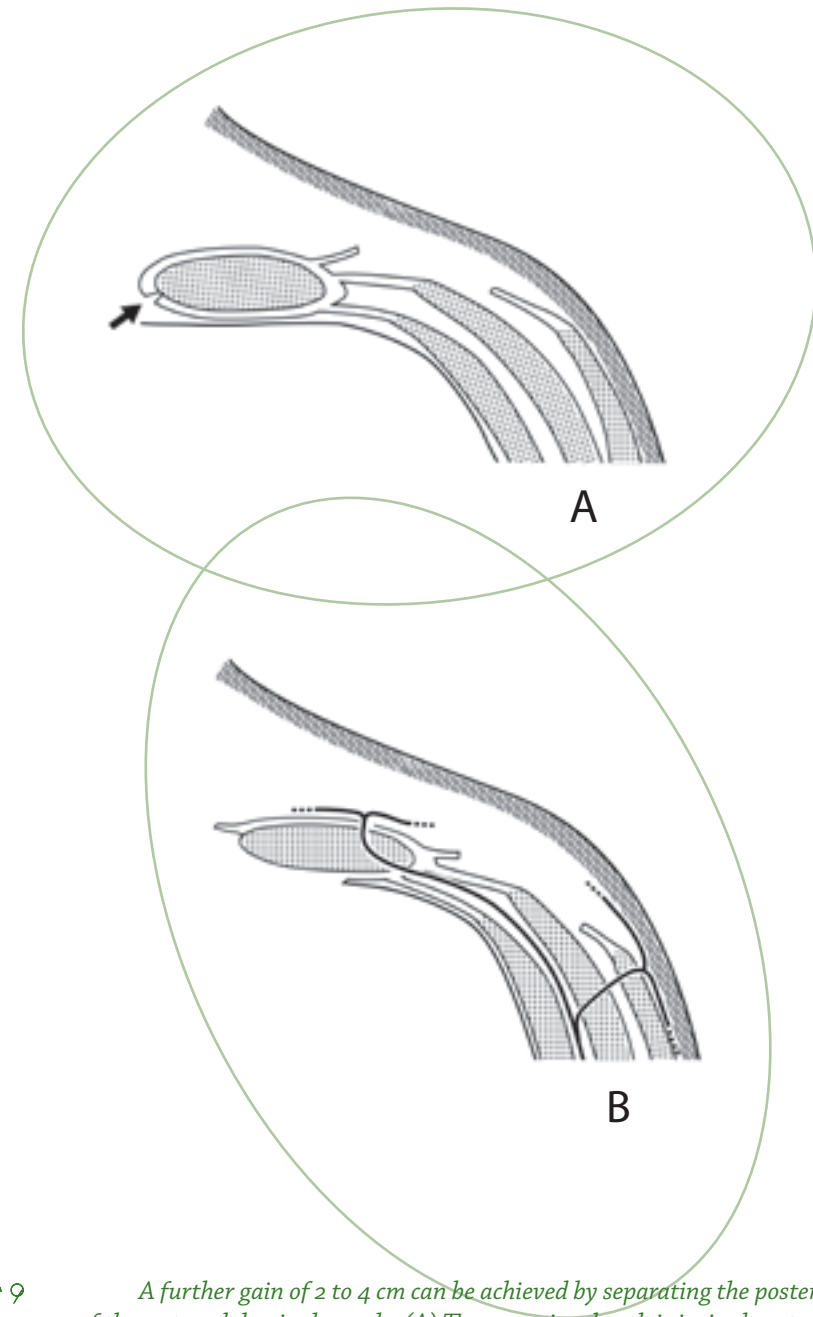
**Figure 6** The aponeurosis of the external oblique muscle is incised 1 to 2 cm lateral to the lateral border of the rectus abdominis muscle. If the aponeurosis is incised correctly fat tissue is seen. If muscles are seen, the incision is most probably not in the correct site.



**Figure 7** The myoaponeurosis of the external oblique muscle is transected longitudinally over its full length. Transection includes the muscular part of the external oblique muscle (a) on the thoracic wall that extends at least 7 to 10 cm cranially. With this extension, the rectus abdominis muscle can be shifted medially maximally in the upper abdomen. The attachment to the ribs must be dissected free to mobilize the rectus abdominis muscle maximally as well.

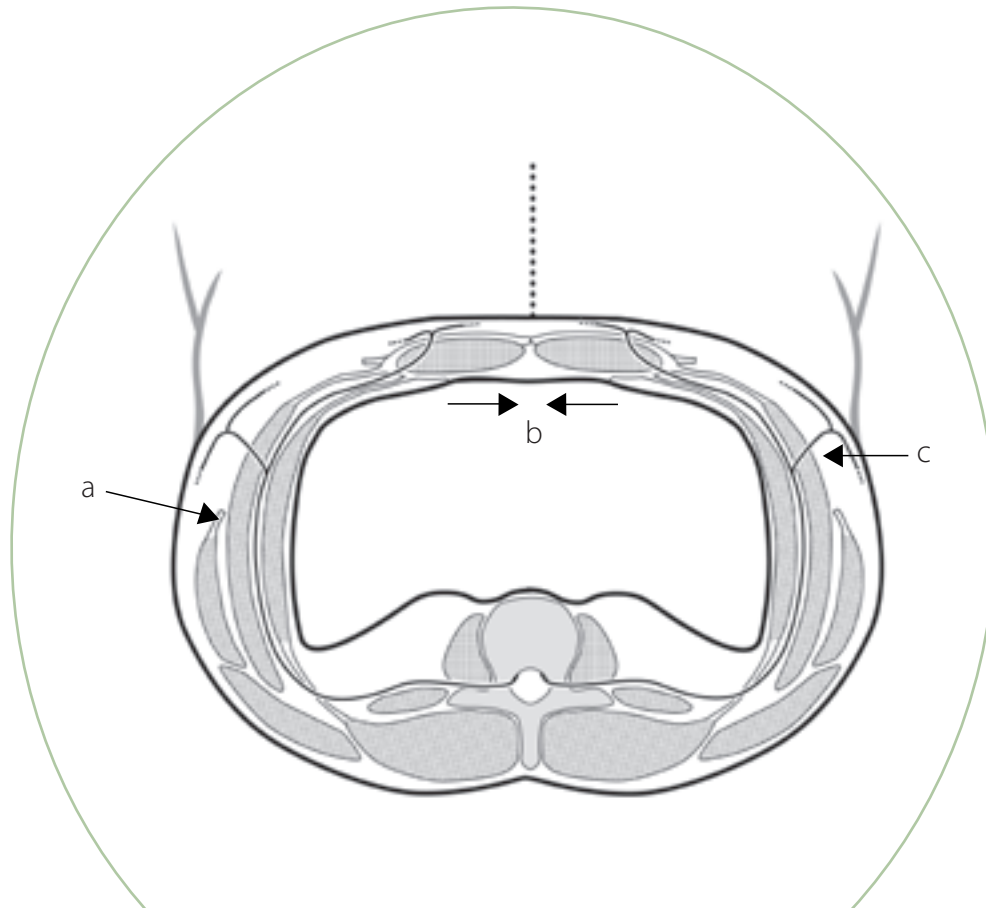


**Figure 8** The external oblique muscle is separated from the internal oblique muscle in the avascular plane between both muscles to the midaxillary line. Mobilization is essential because the fibrous interconnections between both muscles prevent optimal medial shift of the rectus abdominal muscle. It is essential to properly identify the plane between the internal and external oblique muscle. Transection of the internal oblique muscle may result in an abdominal wall rupture because the transversus abdominis muscle is too weak to resist the intra-abdominal pressure. In addition, because the neurovascular bundle runs between the internal oblique and the transversus abdominis muscles, it can easily be damaged, resulting in denervation of the abdominal wall muscles. With this technique, the rectus muscle can be advanced 3 to 5 cm in the upper abdomen, 7 to 10 cm at the waistline, and 1 to 3 cm in the lower abdomen.

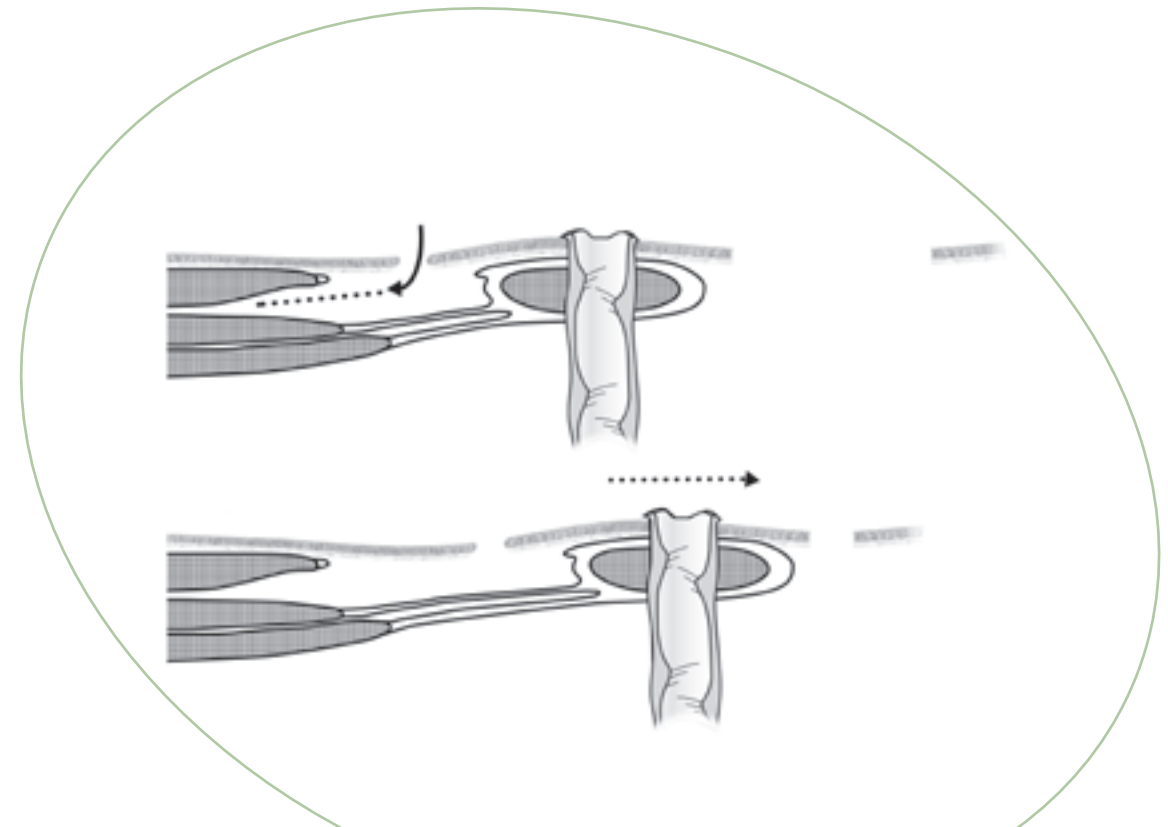


**Figure 9** A further gain of 2 to 4 cm can be achieved by separating the posterior sheath of the rectus abdominis muscle. (A) The posterior sheath is incised posteriorly, near the midline over its full length. The rectus abdominis muscle can easily be separated from the posterior rectus sheath. Attention must be paid not to damage the neurovascular bundle laterally. (B) Note the entrance of the neurovascular bundle that penetrates the fascia of the internal oblique muscle at a variable distance from the lateral border of the rectus abdominis muscle, near the axis of the epigastric artery. Damage to the neurovascular bundle results in denervation of the rectus abdominis muscle.





**Figure 10** The abdominal wall is closed in the midline with a running suture of a nonabsorbable or slowly absorbable suture material, taking big bites of fascia. The length of the suture should be at least 4 times the length of the fascial wound. Suction drains are placed subcutaneously, and the subcutis and skin are closed. Defects up to 28 cm in the waist-line can be bridged in this way. After closure of the abdomen, the external oblique muscle (a) and the posterior rectus sheath (b) are retracted laterally. Transection of the sensory nerves (c) may cause hypoesthesia of the overlying skin.



**Figure 11** In patients with an enterostomy, the technique described cannot be followed, first, because the vascularization of the skin is endangered and, second, because no release of the posterior rectus sheath can be performed. As an alternative, transection of the external oblique aponeurosis is performed through a separate skin incision or through multiple small incision(s) at the lateral aspect of the rectus abdominis muscle. Mobilization of the posterior sheath of the rectus abdominis muscle should not be performed in these cases.

### Postoperative care

Most patients are extubated immediately after the operation. The epidural catheter is left in place for 2 to 3 days postoperatively. The drains are left in place for a maximum of 5 days.

The patient is mobilized on the first postoperative day and instructed in how to prevent undue increased intra-abdominal pressure. Postoperatively, sensory innervation of the ventral abdominal wall is disturbed due to transection of the sensory nerves. A minority of patients complain about bulging of the lateral abdominal wall.



## discussion

The “components separation technique” is useful for the repair of large midline abdominal wall hernias in both clean and contaminated situations. Abdominal wall defects of 25 to 30 cm in the waistline can be bridged with the “components separation technique” (CST); (Table 1).

**table 1** Gain in centimeters after release of the external oblique muscle, without and with release of the posterior rectus sheath (adapted from Taylor et al.<sup>9</sup>).

Gain (in cm) on each side after transection of the external oblique muscle and aponeurosis		
	Without release of the posterior rectus sheath (cm)	With release of the posterior rectus sheath (cm)
Upper abdomen	3-5	4-7
Waistline	7-10	9-14
Lower abdomen	1-3	2-5

The results from the larger series in the literature are listed in Table 2. Reherniation rates in the literature vary between 0 and 8,6%.<sup>10-14</sup> In these series, several modifications are used, including application of prosthetic material. Our own experience is less favorable. In a series of 43 patients in which only a release of the external oblique muscle was performed, we found a reherniation rate of 30%.<sup>15</sup> All patients had small recurrent hernias, the majority of which were located in the upper abdomen. The relatively high recurrence rate may be caused by technical failures; a release of the external oblique muscle on the thorax was not performed in most patients, nor was release of the posterior rectus sheath. In a recent prospective randomized trial comparing CST with bridging the defect with prosthetic material, CST was found to be superior to the insertion of prosthetic material, although a similar reherniation rate was found

**table 2**

Results of the Repair of Large Abdominal Wall Defects with the Component Separation Technique (adapted from de Vries Reilingh et al.<sup>15</sup>).

First Author	Year	Patients	Clean / Contaminated	Complications (n)	Reherniation n (%)	Follow-up mean (range, mo)
Ramirez et al. <sup>6</sup>	1990	11	8/3	0	0 (0.0)	? (4-42)
DiBello et al. <sup>10</sup>	1996	35*	20/15	Wound infection 2 Hematoma 1 Seroma 1	3 (8.6)	22 (1-43)
Giroto et al. <sup>11</sup>	1999	33	30/3	Wound infection 8 Enterocutaneous fistula 1	2 (6.1)	21 (6-57)
Shestak et al. <sup>12</sup>	2000	22	?	Wound infection 2 Seroma 1 Death 1	1 (5)	52 (8-84)
Lowe et al. <sup>13</sup>	2000	30**	?	Wound infection 12 Skin ischemia 6 Skin dehiscence 13	3 (10)	12
Cohen et al. <sup>14</sup>	2001	24	15/9	Skin dehiscence 2 Seroma 1	1 (4)	? (12-36)
De Vries Reilingh et al. <sup>15</sup>	2003	43	28/15	Wound infection 6 Hematoma 5 Seroma 2 Skin necrosis 1 Fascial dehiscence 1	12 (30)	15.6 (12-30)

\* In 15 patients, an onlay synthetic prosthesis was implanted as well.

\*\*In 10 patients, an onlay polypropylene mesh was implanted as well.

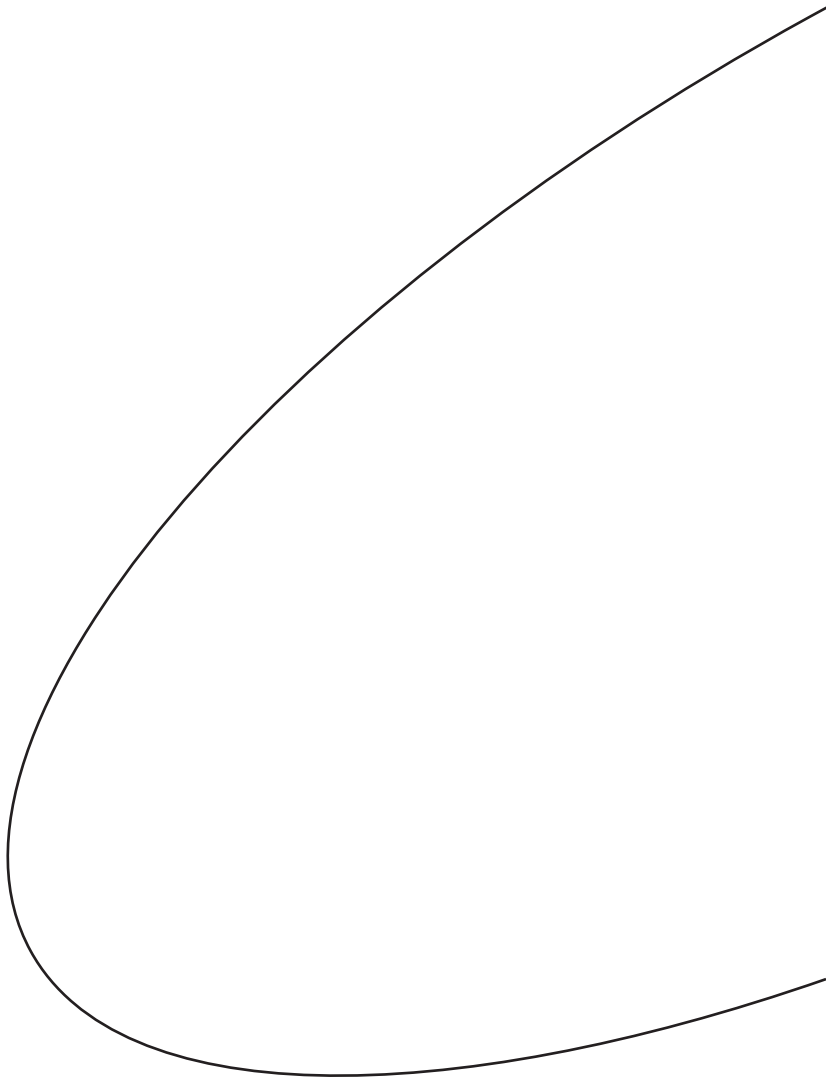
after a follow-up of 24 months.<sup>16</sup> Recently, a prospective randomized multicenter trial was initiated to compare CST with and without insertion of a preperitoneal polypropylene mesh.

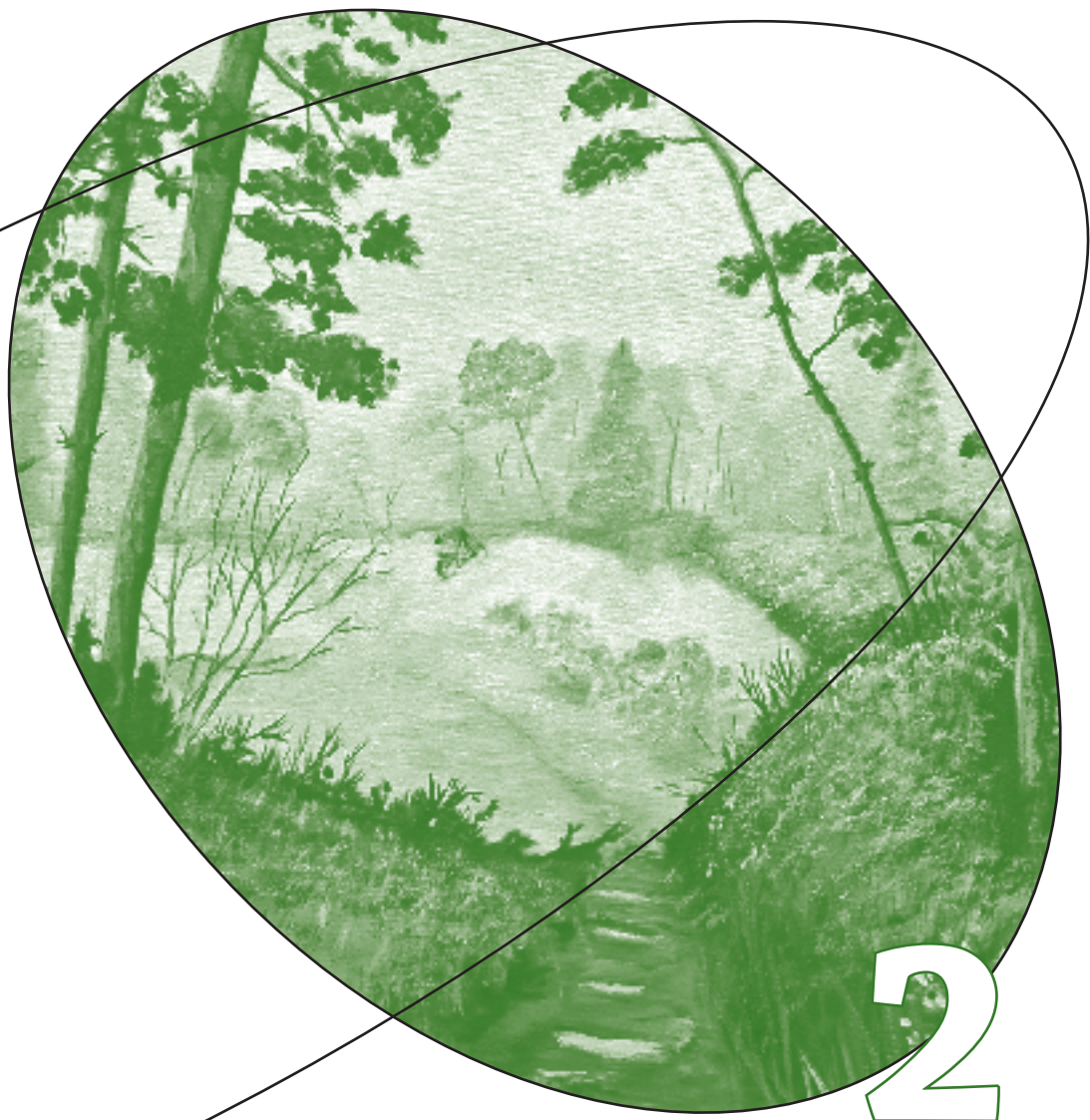
Wound complications are rather frequent due to the creation of large wound surfaces. Hematoma and seroma formation are the most frequent complications, whereas infections are reported in 0% to 40% of patients (Table 2). In most cases, these complications can be treated conservatively. To diminish wound-related complications and to preserve vascularization of the skin, we developed a minimally invasive technique to transect the external oblique muscle. A balloon is introduced between the external and internal oblique muscle via a separate incision. The space between both muscles is mobilized by inflation of the balloon. Then, the external oblique muscle can be separated under vision with a 30° laparoscope.<sup>8</sup>

In conclusion, CST is a useful technique to repair large midline hernias without the use of biomaterials.

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## "components separation technique" for the repair of large abdominal wall hernias

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## introduction

Reconstruction of large, midline abdominal wall hernias is still a major problem in general surgery. Reherniation rates of up to 46% have been reported after primary closure, so reconstruction with prosthetic material is preferred.<sup>1,2</sup> Most of these defects cannot be closed primarily because the fascial edges are retracted far laterally into the flank from to shortening of the external oblique muscle.<sup>3</sup> To overcome this problem, biomaterials are widely used to bridge these defects.<sup>4</sup> For this purpose, polypropylene mesh is still the most widely used material. Preperitoneal or submuscular implantation of the mesh following Stoppa<sup>5</sup> and Rives<sup>6</sup> has favorable results with reherniation rates of 15% - 24%.<sup>2</sup>

If meshes are used, the greater omentum or peritoneum must be interponated between the bowels and the mesh to prevent adhesions and erosion of the bowels. Also, infection and the need for full thickness skin coverage are other major drawbacks of this method, especially if reconstructions are performed in the presence of contamination or infection.<sup>6</sup>

In 1990, Ramirez and colleagues<sup>3</sup> developed a technique for reconstruction of abdominal wall defects without the use of prosthetic material. This technique is based on enlargement of the abdominal wall surface by translation of the muscular layers. After mobilization of the skin, the external oblique muscle is transected just laterally from its insertion into the rectal sheath and separated from the internal oblique muscle (Figure 1). Then the rectus abdominis sheath is advanced medially. In this way, defects of up to 20 cm at the waistline can be bridged.

It is the aim of this study to determine the early and late results of the technique.

## methods

From July 1994 to August 1999, 43 large abdominal wall hernias were repaired, using the "components separation technique" without release of the posterior rectus sheath, in 43 patients. There were 11 women and 32 men with a mean age of 49.7 years (range 22 to 78 years). All patients had midline hernias that could not be closed primarily. The patients were operated on in the Twenteborg Hospital, Almelo (n = 5; RPB), VU



University Medical Center Amsterdam (n = 10; RPB), Radboud University Nijmegen Medical Center (n = 13; HvG), University Medical Center Groningen (n = 9; CR) and Atrium Medical Center Heerlen (n = 6; MHAB); in The Netherlands.

The operations were performed on patients with a midline incisional hernia that could not be closed primarily and in whom mesh repair was contraindicated because of infection, contamination, or absence of the greater omentum to interpose between mesh and bowels.

The records of these patients were reviewed and all patients were invited to come to the outpatient clinic to determine the condition of the abdominal wall. The following data were extracted from the medical record: body length and weight, size and cause of the hernia, per- and postoperative mortality and morbidity, with special attention paid to wound and pulmonary complications.

## operative technique

After midline laparotomy or removal of the split skin graft from the bowels, the abdominal cavity is entered. The bowels are dissected free from the ventral abdominal wall. The skin and subcutaneous fat are dissected free from the anterior rectus sheath and the aponeurosis of the external oblique muscle (Figure 1A). Since the perforating branches of the epigastric artery are transected, the blood supply of the skin is at risk, because then it solely depends on the intercostal arteries and branches of the pudendal artery. Subsequently, the aponeurosis of the external oblique muscle is transected longitudinally about 2 cm laterally from the rectus sheath (Figure 1B and C), including the muscular part that inserts on the thoracic wall, which extends at least 5 to 7 cm cranially of the costal margin (Figure 1D). The external oblique muscle is separated from the internal oblique muscle, as far laterally as possible. In this way, a gap of 14 to 20 cm can be bridged at the waistline. If primary closure is impossible with undue tension, a further gain of 2 to 4 cm can be reached by separation of the posterior rectal sheath from the rectus abdominal muscle (Figure 1E). Care must be taken not to damage the blood supply and the nerves that enter the rectus abdominal muscle at the posterior side. Vacuum drains are left behind in all patients, subcutaneously. In all patients, the fascia and skin are closed with a running polydioxanone suture (PDS-loop, Ethicon, Johnson & Johnson Medical, Norderstedt, Germany), without undue tension. No specific instructions are given to the patient after the operation.

Figure 1

Technique of the “components separation technique” following Ramirez and colleagues<sup>3</sup>

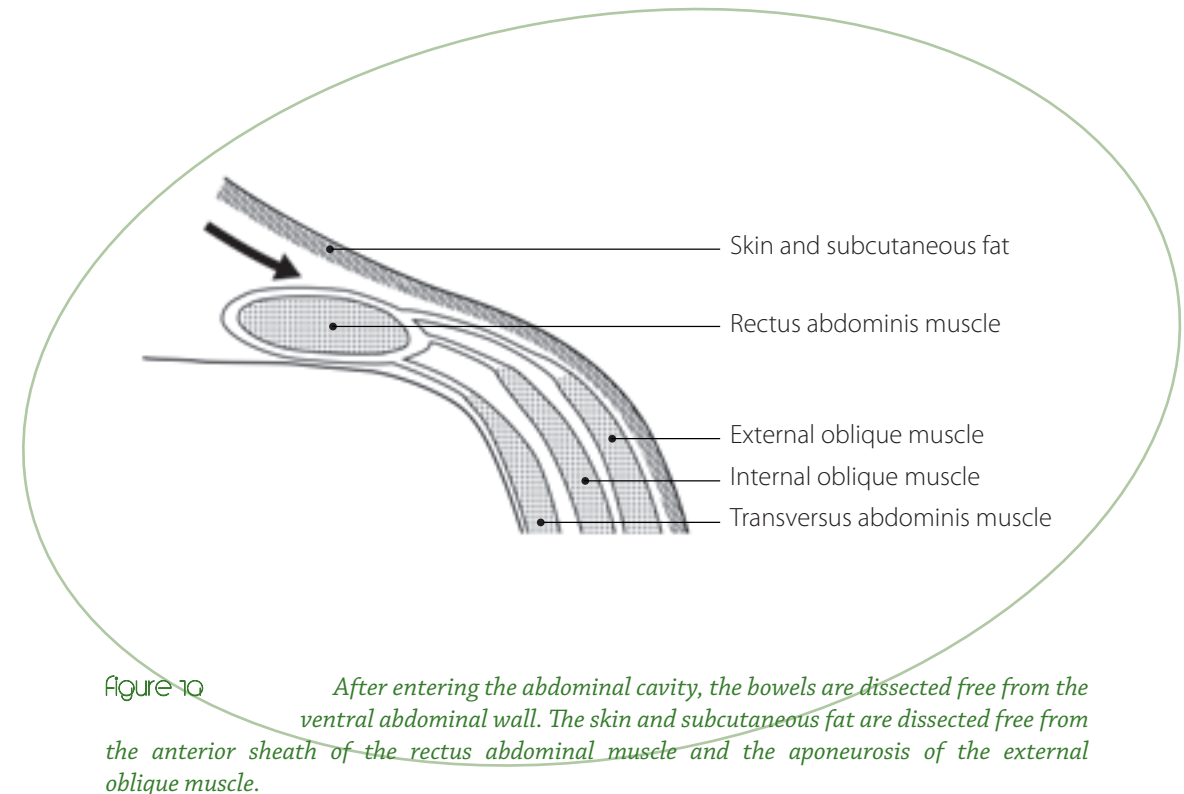


Figure 1A

After entering the abdominal cavity, the bowels are dissected free from the ventral abdominal wall. The skin and subcutaneous fat are dissected free from the anterior sheath of the rectus abdominal muscle and the aponeurosis of the external oblique muscle.



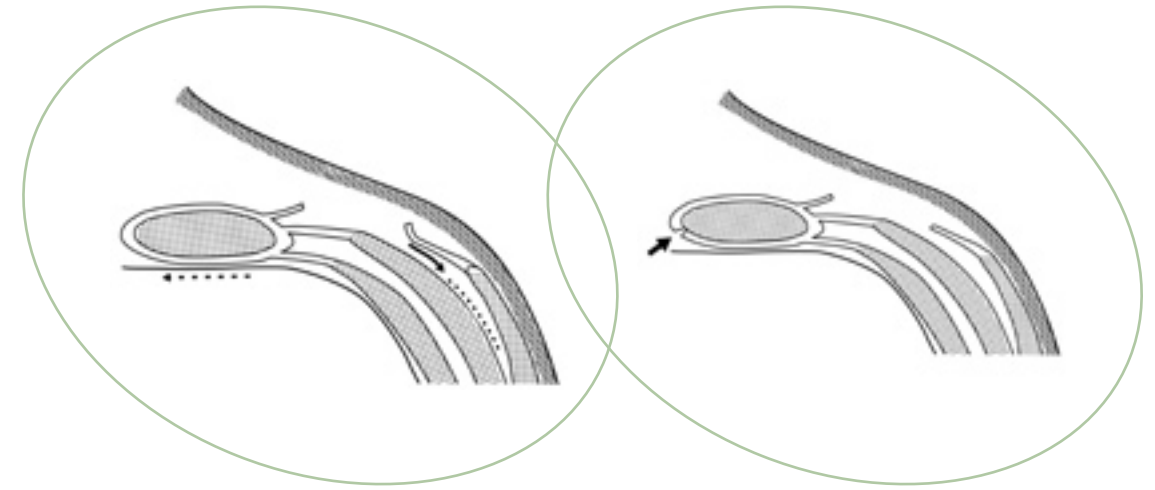
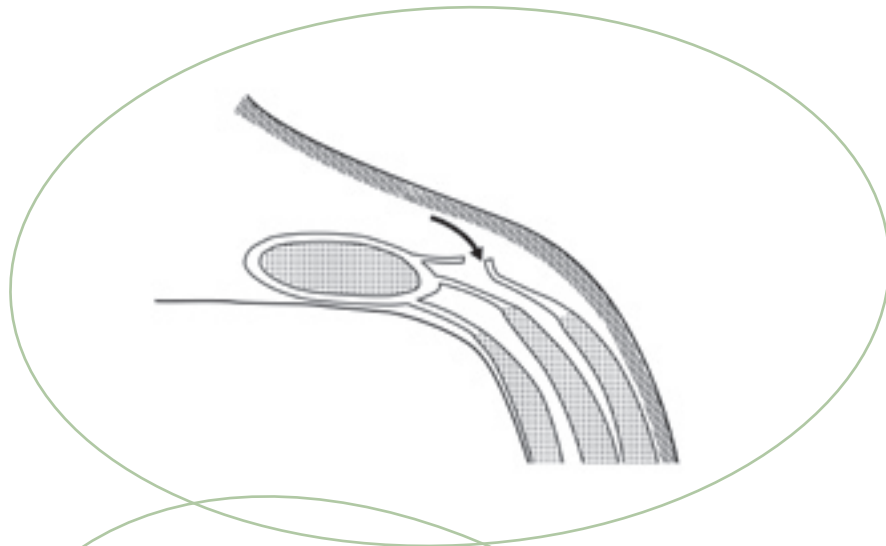


Figure 10

*The external oblique muscle is separated from the internal oblique muscle, as far laterally as possible.*

Figure 11

*If primary closure is impossible with undue tension, a further gain of 2 to 4 cm can be reached by separation of the posterior rectal sheath from the rectus abdominis muscle. Care must be taken not to damage the blood supply and the nerves that run between the internal oblique and transverse muscle and enter the rectus abdominis muscle at the posterior side.*

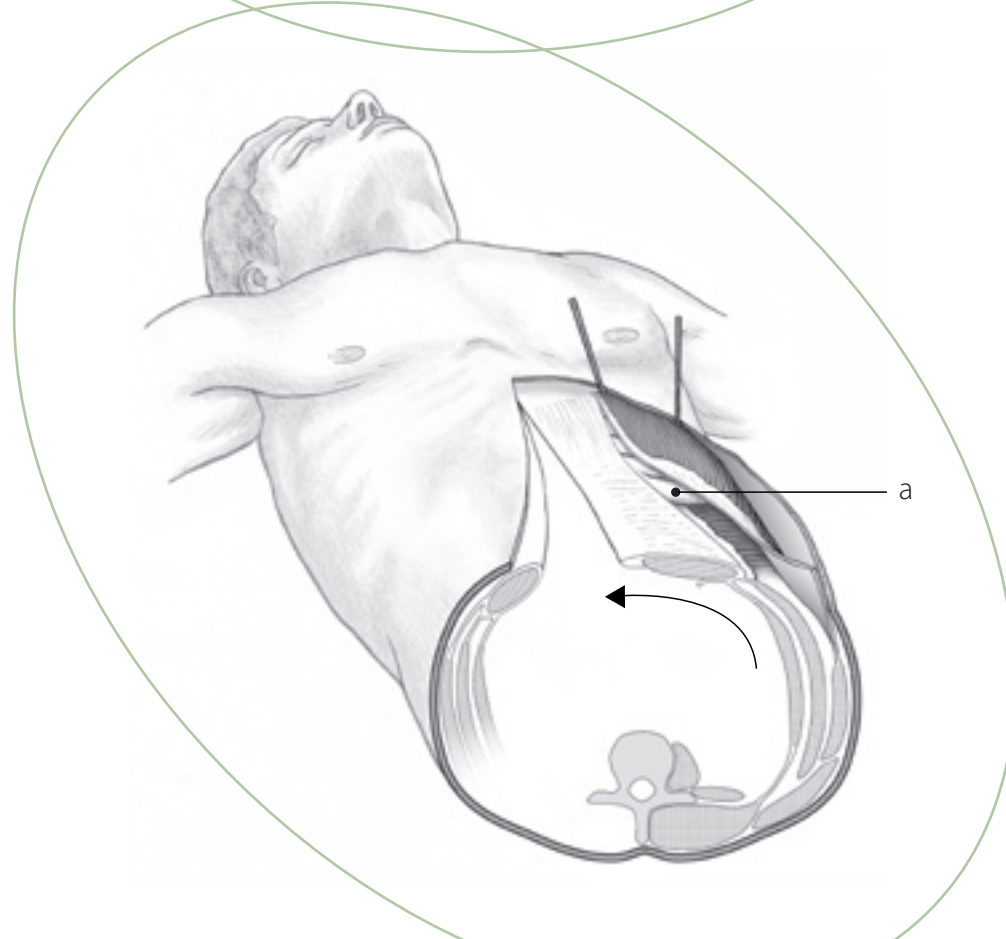


Figure 12 + 13

*The aponeurosis of the external oblique muscle is transected longitudinally about 2 cm lateral from the rectus sheath, including the muscular part on the thoracic wall, which extends at least 5 to 7 cm cranially of the costal margin.*

## results

Reconstruction of a large midline hernia was performed in 43 patients. The mean length of the defect  $\pm$  1 standard deviation was 18 cm  $\pm$  6, the mean width of the defect was 13 cm  $\pm$  7. The mean body mass index (body weight/(length)<sup>2</sup>)  $\pm$  1 standard deviation was 27.3 kg/m<sup>2</sup>  $\pm$  4.5. The defect resulted after elective surgery in 19 patients and acute surgery in 24 patients. In 11 patients, the defect was a result of open treatment of generalized peritonitis. Thirteen patients had a recurrent incisional hernia, nine after reconstruction with prosthetic material (polypropylene mesh or expanded polytetrafluoroethylene patch).

Reconstruction was performed under clean conditions in 28 patients, clean-contaminated in ten, and contaminated or dirty in five. In 15 patients, the reconstruction was combined with bowel surgery. In three patients, continuity of the colon was restored after Hartmann's procedure. In six patients, continuity of the small bowel was restored; in two, an ileostomy was dismantled and in four, multiple enterocutaneous fistulas were repaired. In five patients, an enterostomy was repositioned: three colostomies and two uretero-ileo-cutaneostomies following Bricker.

In thirty-eight of the 43 patients, the classical technique as described by Ramirez and colleagues<sup>3</sup> was used. In five patients a transection of the aponeurosis of the external oblique muscle was done via a separate incision as described previously.<sup>8</sup>

The postoperative course was uneventful in 25 patients (58.1%). One patient died on the sixth postoperative day as a result of massive bowel necrosis from mesenteric thrombosis. Wound complications occurred in 14 patients (32.6%): five had a hematoma, two a seroma, one had skin necrosis at the midline, and six patients had a wound infection. Three wound infections occurred in the group of 28 patients in whom the reconstruction was done under clean conditions and in three patients in whom the reconstruction was done under contaminated or dirty conditions. Two patients developed respiratory insufficiency from a combination of increased intra-abdominal pressure and pre-existing pulmonary disease. In one patient, a rupture of the abdominal wall at the site of the relaxing incision occurred on the first postoperative day. During re-operation it was found that both the external and internal oblique muscle had been transected, resulting in a rupture of the transverse abdominal muscle. The defect was repaired with an onlay polypropylene mesh.

In the outpatient clinic, 38 of the 42 surviving patients were seen at least one year after operation. The mean follow-up of these patients was 15.6 months (range 12 to 30 months). Twelve of the 38 patients (32%) had a recurrent hernia. Recurrences occurred after a mean period of 13.4 months (range 2 to 24 months). Until now, none of the patients had complaints and had to be re-operated. Recurrence in 6 of the 12 patients occurred after removal of prosthetic material implanted during previous hernia operations. Recurrence of the hernia tends to occur more frequently in morbidly obese patients (mean body mass index 30.1 kg/m<sup>2</sup> in recurrence group versus 25.6 kg/m<sup>2</sup> in non-recurrence group). Two of the six patients with a wound infection and 2 of the 15 patients who underwent a reconstruction in a contaminated environment had a recurrent hernia. The remaining 4 of 42 patients with less than one year follow-up (1, 1, 3 and 4 months, respectively) had no recurrent hernia.

## discussion

The “components separation technique” described by Ramirez and colleagues<sup>3</sup> is useful for the repair of large abdominal wall defects under clean and contaminated conditions, although the reherniation rate is relatively high.

In the article by Ramirez and colleagues<sup>3</sup>, the results of the technique in the first 11 patients was reported. In seven patients, the technique was used unilaterally after transverse rectal abdominis muscle flap harvesting for reconstructive surgery, and in three patients, the technique was used bilaterally. No complications were reported, and reherniation was not found after a follow-up of 4 to 42 months. Since then, six series have been published about the results of the components separation technique (Table 1).<sup>3,9-13</sup> DiBello and Moore<sup>9</sup> used a modified technique in 35 patients, in 20 under clean and in 15 under contaminated conditions (Table 1). In none of the patients was a release of the posterior rectal sheath done, and in fifteen patients midline closure was supported by an onlay prosthesis of expanded polytetrafluoroethylene (n = 3) or a Vicryl mesh (Ethicon, Johnson & Johnson Medical) (n = 12). Postoperative wound complications were reported in 14% and reherniation was found in 9% after a mean follow-up of 22 months. Girotto and coworkers<sup>10</sup> applied the original technique in 30 patients under clean conditions and in three in the presence of infection. Postoperative wound complications were reported in 27%, with reherniation in 6% after a mean follow-up of 21 months. Shestak and colleagues<sup>11</sup> applied the same technique as DiBello and Moore<sup>9</sup> in 22 patients. Postoperative wound complications were reported in 14%. One patient died during the operation because of multiple organ failure. Reherniation was found in 5% after a mean follow-up of 52 months.

Postoperative complications were more frequent in the series of Lowe and colleagues<sup>12</sup>, who reported about 30 patients. In 20 patients, the original technique was performed, in 10 patients, an onlay polypropylene mesh was used as well (Table 1). Reherniation was found in 10% of the patients after a mean follow-up of 12 months. The results of our multicenter study corroborate these studies, although the reherniation rate in our series is higher than in other series (Table 1). But, comparison of the reherniation rates is hampered by the incomplete data on the size of the initial hernias in two series and by the unknown follow-up procedure in all series.

Most patients in our series had large hernias and in none of the patients could the fascia be closed primarily. Although transection of the myoaponeurosis of the external oblique muscle made primary closure possible, the fascia was closed without undue tension in all patients. Most recurrences were found in the upper abdomen. Reherniation might be the result of insufficient release of the external oblique muscle at its insertion on the thoracic wall. With growing experience, it was recognized that complete transection of the external oblique muscle on the thoracic wall, over a distance of at least 5 cm cephalad of the costal margin, was of utmost importance to prevent undue tension on the fascia in the upper abdomen. The lower reherniation rates in the other series might also be explained by the use, in some patients, of onlay synthetic

Table 1 Results of the Repair of Large Abdominal Wall Defects with the “Components Separation Technique”.

First Author	Year	Patients	Clean / Contaminated	Complications (n)	Reherniation n (%)	Follow-up mean (range, mo)
Ramirez et al <sup>3</sup>	1990	11	8/3	0	0 (0.0)	? (4-42)
DiBello et al <sup>9</sup>	1996	35*	20/15	Wound infection Hematoma Seroma	2 1 1	22 (1-43)
Giroto et al <sup>10</sup>	1999	33	30/3	Wound infection Enterocutaneous fistula	8 1	21 (6-57)
Shestak et al <sup>11</sup>	2000	22	?	Wound infection Seroma Death	2 1 1	52 (8-84)
Lowe et al <sup>12</sup>	2000	30**	?	Wound infection Skin ischemia Skin dehiscence	12 6 13	12
Cohen et al <sup>13</sup>	2001	24	15/9	Skin dehiscence Seroma	2 1	? (12-36)
de Vries Reilingh et al	2003	43	28/15	Wound infection Hematoma Seroma Skin necrosis Fascial dehiscence	6 5 2 1 1	15.6 (12-30)

\* In 15 patients, an onlay synthetic prosthesis was implanted as well.

\*\*In 10 patients, an onlay polypropylene mesh was implanted as well.

meshes to support the abdominal wall. Omitting release of the posterior rectal sheath in most of our patients, as in the series of DiBello and Moore<sup>9</sup>, is probably not an explanation for the higher reherniation rate in our series.

Although the “components separation technique” is an attractive method for the reconstruction of abdominal wall defects, this method has three major disadvantages. First, the reherniation rate is relatively high. This might be related to the rather complex hernias, which were included in the study, and the 35% of reconstructions that were done under contaminated conditions. Because no reasonable alternative for reconstruction under these circumstances is available, the “components separation technique” seems to be valuable.

Second, the skin and subcutaneous tissue must be mobilized over a large distance to reach the aponeurosis of the external oblique muscle, which is retracted far laterally into the flank. This creates a large wound surface that covers the whole ventral abdominal wall from the costal margin to the pubic bone and predisposes to hematoma and seroma formation and infection. Also, mobilization of the skin and subcutaneous tissue endangers its blood supply, which can lead to skin necrosis in the midline. If the musculo-cutaneous perforators of the epigastric artery are transected, the blood supply of the skin depends solely on the intercostal arteries. Interference with the blood supply from the intercostal arteries by scars, enterostomies, or even drains can result in skin necrosis, as was found in 20% of the patients in the study by Lowe and colleagues.<sup>12</sup> Third, the technique destabilizes the outer layer of the abdominal wall, allowing shifting of the skin in relation to the underlying myoaponeurotic tissue. This makes application in patients with enterostomies difficult. Under these circumstances, we now use a modified technique in which separate incisions are made just lateral to the rectus sheath for transection of the aponeurosis of the external oblique muscle. In this way, the wound surface is markedly reduced and the blood supply to the skin via the dominant musculo-cutaneous perforators of the epigastric artery is preserved. A well-vascularized compound flap is created that can be advanced to the midline. Existing enterostomies can be left in place and new enterostomies are facilitated because shifting of the skin in relation to the rectus muscle has been prevented.<sup>8</sup> Recently, we have performed endoscopically assisted transection of the aponeurosis of the external oblique muscle. Via a 2-cm skin incision, a balloon is introduced in the space between the internal and external oblique muscle. Subsequently, the plane between the external and internal oblique muscle is dissected free by balloon dilatation, followed by transection of the external oblique muscle under video-endoscopic control. This saves the circulation via the intercostal arteries, diminishes the wound

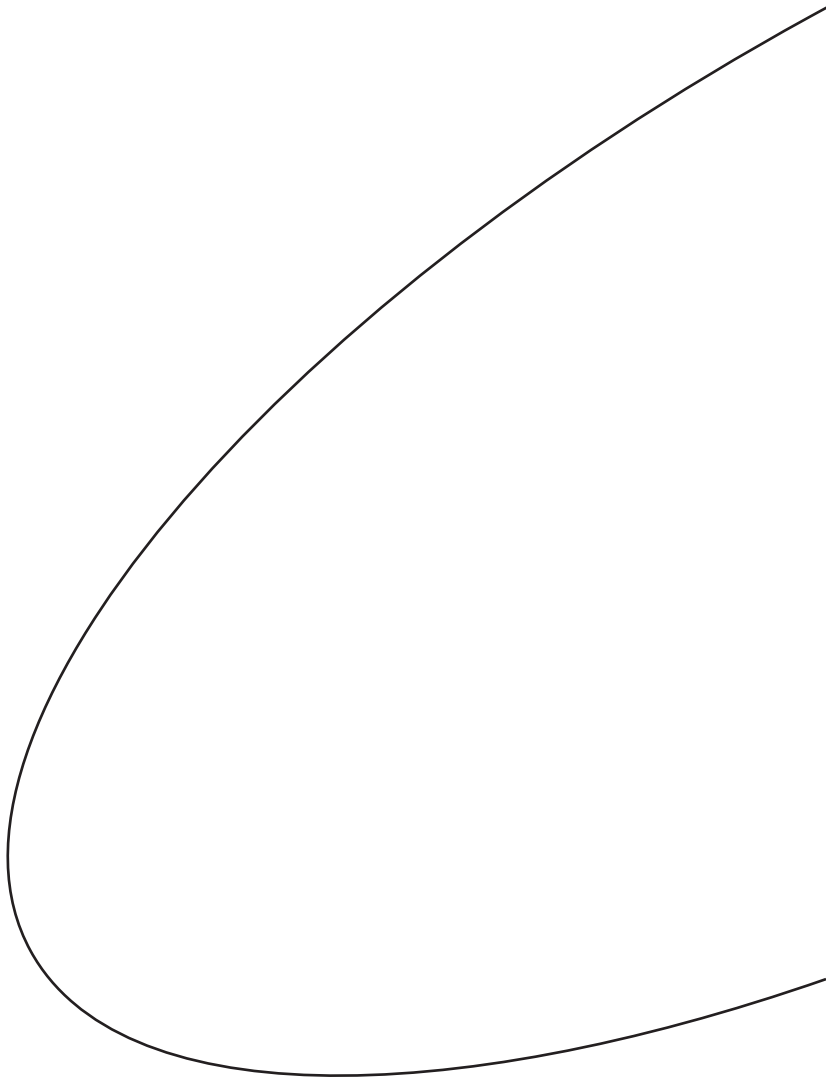
surface, and improves the cosmetic result. Until now, we used this technique in five patients. No wound or other complications occurred during the postoperative course and all enterostomies functioned well.<sup>14</sup>

The results of this study corroborate the results of a series of 53 patients with large midline incisional hernias, that were reconstructed using a polypropylene mesh. In this series, we found 41% wound complications and a reherniation rate of 28%.<sup>15</sup>

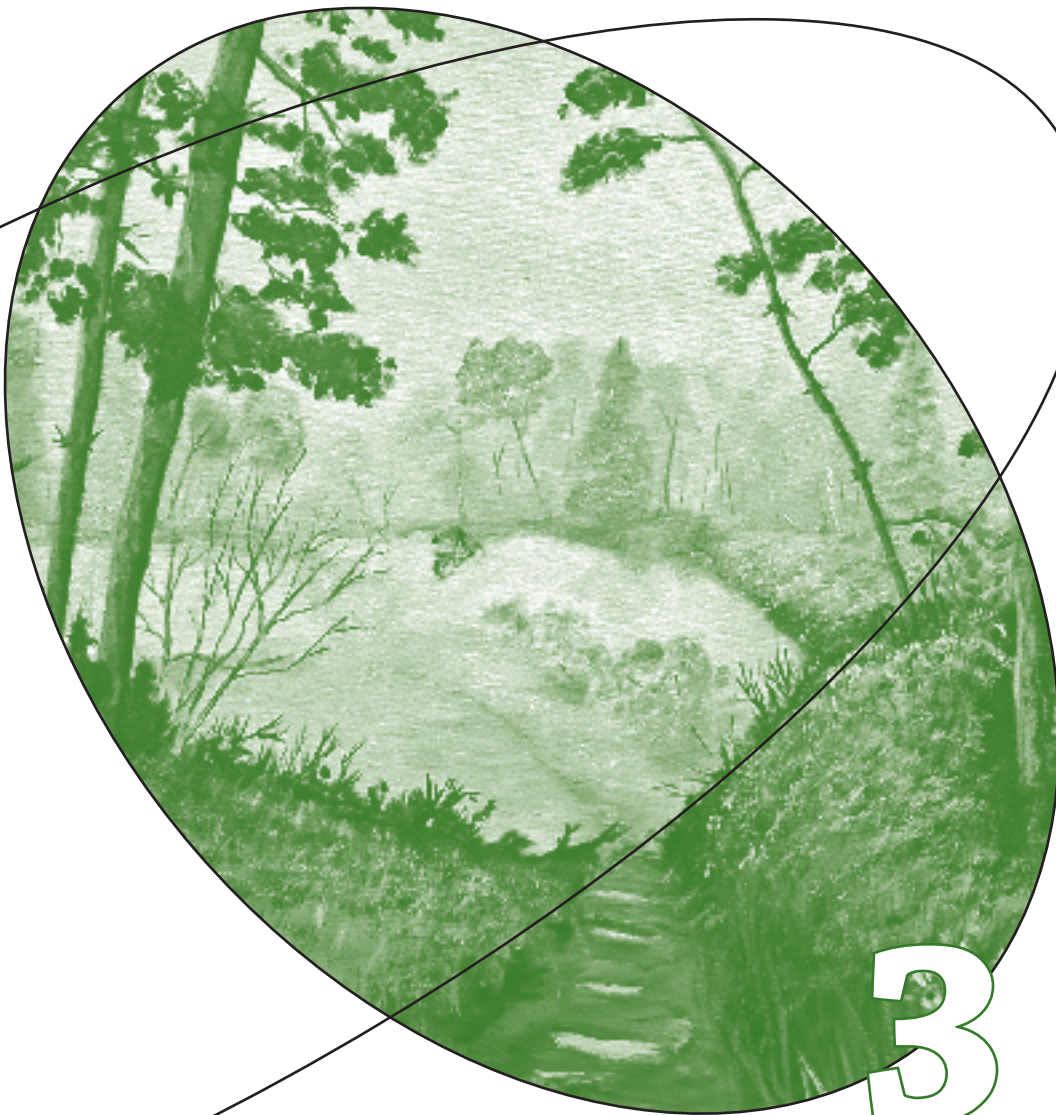
In conclusion, the “components separation technique” is an attractive method for the repair of large midline hernias, especially when the use of biomaterials is contraindicated. Modifications of the technique, such as support by onlay prosthetics to decrease reherniation rate and transection of the external oblique muscle via separate incisions to diminish the extent of dissection need further research.

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## autologous tissue repair of large abdominal wall defects: a review

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## introduction

Reconstruction of large abdominal wall hernias that cannot be closed primarily poses technical challenge. Many surgeons discourage patients from undergoing abdominal wall reconstruction because of this, and the high morbidity and the relatively high recurrence rates. Patients however, may have large hernias causing: bulging of the abdominal wall, chronic wounds, immobility and back pain, necessitating surgical treatment. Moreover, a growing number of patients surviving intra-abdominal catastrophes have abdominal wall defects with associated chronic infection and/or enterocutaneous fistula - features that complicate abdominal wall reconstruction.

Bridging the fascial gap with prosthetic material is still the most frequently applied method of reconstruction, but prosthetic materials have several drawbacks.<sup>1,2</sup> First, they may alter the mechanical properties of the abdominal wall, providing less dynamic support and a less favourable cosmetic result owing to bulging of the prosthesis. Second, the material may damage the intra-abdominal viscera if the peritoneum or greater omentum cannot be interposed between it and the intra-abdominal viscera.<sup>3</sup> Third, implantation of biomaterials is accompanied by an increased risk of infection, particularly when they are used for reconstruction in a contaminated or dirty environment, such as the abdominal wall in the presence of an enterocutaneous fistula.<sup>4,5</sup>

Reconstruction of very large abdominal wall defects is usually done by a multidisciplinary team that includes general surgeons, plastic and reconstructive surgeons, anaesthetists and intensive care physicians. This review focuses on the results of the surgical technique to repair abdominal wall defects with autologous tissue in patients in whom primary closure of the abdomen is impossible, using the “components separation technique”, da Silva technique, free fascia lata graft, autodermal graft and pedicled or free vascularised myo-fascial(-cutaneous) flaps. Pre-operative preparation and post-operative care are not considered.

## methods

### Search strategy

An electronic search of Medline and PubMed databases was conducted using the following keywords: “components separation technique” (CST), Ramirez (technique), da Silva (technique), fascia lata, tensor fasciae latae, latissimus dorsi, rectus femoris,

myocutaneous flap, myofasciocutaneous flap, ((auto) dermal) grafts, dermoplasty, cutisplasty, hernia and abdominal wall defect. These terms were mapped to Medline Subjects Headings (MeSH) terms as well as being searched for as text items. Only publications in English or German were used and publications before 1979 were excluded.

Relevant publications were acquired after assessing the titles and abstracts. A manual search of references from these publications was also performed to find additional articles.

### Critical appraisal

All selected papers, except case reports and case series, were evaluated for methodological quality according to the methodological index for non-randomized studies (MINORS-index).<sup>6</sup> This consists of eight or 12 items, each of which can be scored by a three-point scale, varying from 0 to 2, with 0 indicating that the item was not reported in the paper under evaluation, 1 indicating that it was reported, but inadequately, and 2 indicating that it was reported adequately. Eight items apply to non-comparative studies and four additional items to comparative studies. Hence, the maximum score is 16 for non-comparative studies and 24 for comparative studies. The MINORS-index has been shown to be a valid instrument for assessing the methodological quality of non-randomized, comparative and non-comparative trials in surgery, developed for use by readers, manuscript reviewers or journal editors.

Three authors (TVR, MEB and RPB) produced the MINORS-index score for all selected publications. Definitive MINORS-indices were established after reaching consensus between these three authors.

### Data extraction

Data were extracted only from full articles: study design, year of publication, number of patients included and evaluated, demographic details, surgical technique, mortality, morbidity, re-interventions, reherniation rate, and duration and method of follow-up. Mortality was defined as in-hospital mortality. In-hospital morbidity was divided in post-operative wound complications and medical complications.

### Analysis

The incidence and 95% confidence interval (c.i.) for wound complications and reherniation after CST were calculated from the pooled patient data according to the method

of DerSimonian and Liard using those publications that gave adequate information on the specific item, based on the MINORS-index.<sup>7</sup> Both duration and method of follow-up are critical factors to determining reherniation rate. Adequate follow-up was defined as physical examination of the abdominal wall at least 1 year after operation. It is clearly stated in the text if these criteria were not met.

The number of publications and number of patients are given separately, for each item. A random-effects meta-analysis was conducted using StatsDirect statistical software (StatsDirect, Altrincham, UK).

The number of publications on the da Silva technique (two), fascia lata graft (four), autodermal graft (three), pedicled musculocutaneous flap (three) and free vascularized musculocutaneous flap (11) was too small to permit analysis along the same lines as for CST. These techniques are therefore described without analysis.

## Local tissue repair

### “Components Separation Technique”

Ramirez, Ruas and Dellon first described CST for the repair of large ventral hernias in 1990.<sup>8</sup> It is based on enlargement of the abdominal wall surface by moving the muscular layers to bridge a fascial defect up to 20 cm at the waistline.

The method and its modifications has been described in detail by Ramirez et al., Bleichrodt et al., de Vries Reilingh et al. and Maas et al. (Figure 1).<sup>8-12</sup>

The CST may be used to repair large midline hernias by shifting the retracted rectus abdominis muscle to the midline. This is achieved by vertical transection of the external oblique muscle and the posterior rectus sheath. Transection of the external oblique muscle alone enables a shift of the rectus of 7-10 cm at the waistline on each side. A further gain of 2-4 cm is obtained by transection of the posterior rectus sheath. For very large hernias, transection of the transverse abdominis muscle give extra gain.<sup>13</sup>

Figure 1

"components separation technique"

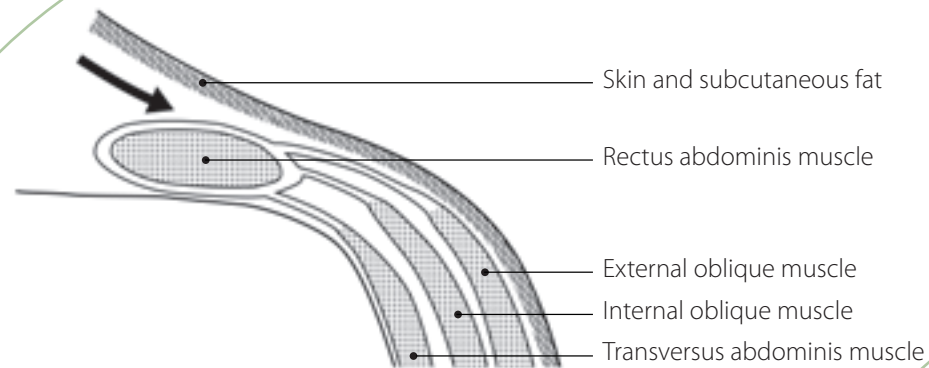


Figure 10

After opening the abdomen, the bowels and other viscera are dissected free from the ventral abdominal wall. The skin and subcutaneous fat are dissected free from the anterior rectal sheath and the aponeurosis of the external oblique muscle (arrow).

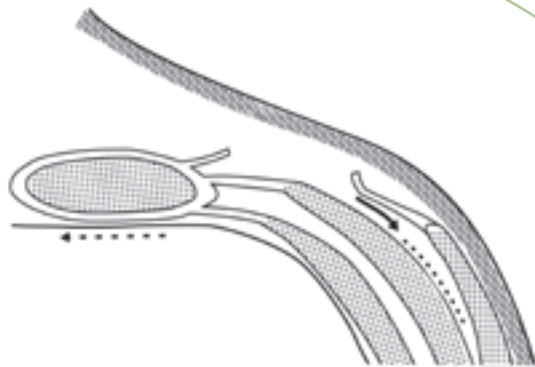


Figure 10

The aponeurosis of the external oblique muscle is incised 2 cm lateral to the lateral border over its full length, including the muscular part of the external oblique muscle on the thoracic wall. The external oblique muscle is separated from the internal oblique muscle in the avascular plane between both muscles (arrow). The rectus muscle can now be advanced in the midline (dotted arrow).

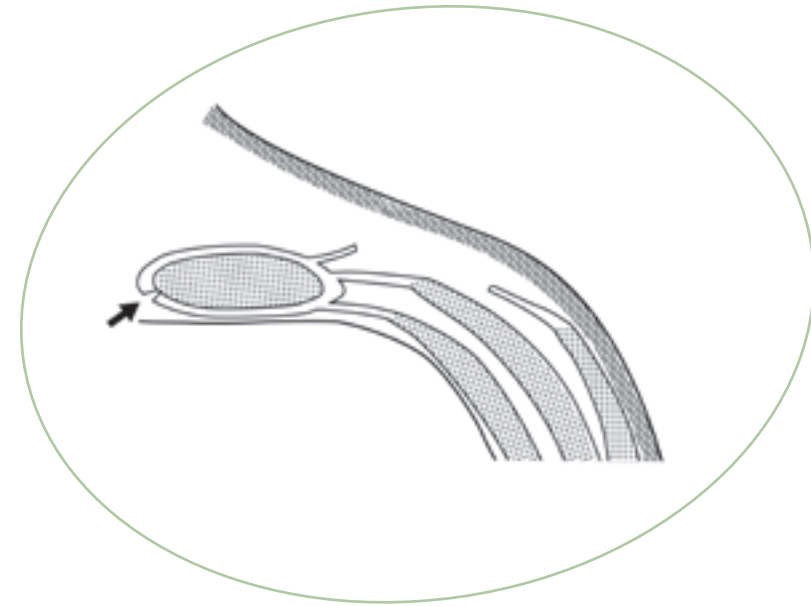


Figure 10

The rectus muscle can be advanced 3-5 cm in the upper abdomen, 7-10 cm at the waistline and 1-3 cm in the lower abdomen. A further gain of 2 to 4 cm can be achieved by separation of the posterior sheath of the rectus abdominal muscle (arrow). The abdominal wall can be closed by approximation of the anterior rectus sheath.

Fifteen series reporting the results of abdominal wall repair using the CST, one randomized controlled trial (RCT) and 14 retrospective series, were found in the literature. (Figure 2)<sup>5,8,10,13-25</sup> In all studies transection of the external oblique muscle was performed. In six, a release of the posterior rectus sheath was also carried out, when necessary<sup>10,17,21-24</sup> and in two studies a release of the anterior rectus sheath was described.<sup>13,15</sup> In one series, transection of the transverse abdominal muscle was done in combination with transection of the external oblique muscle and the posterior rectus sheath, in selected patients.<sup>13</sup> In three series, incidental prosthetic onlay mesh support was used in patients with a fascia of poor quality or to bridge the defect in combination with the CST.<sup>14,17,22</sup>

De Vries Reilingh et al. carried out a RCT comparing CST and prosthetic repair in patients with giant midline abdominal wall hernias. Both procedures produced a similar high wound complication rate: hematoma in 5%, seroma in 28%, skin necrosis 13% and wound infection in 5%.<sup>5</sup> These complications had major consequences for patients who underwent prosthetic repair, as the prosthesis had to be removed owing to infection in 38%. Reherniation, including that in patients with explanted the prostheses, occurred in 60% after prosthetic repair and 53% after CST, at a follow-up of 36 months. All hernias in the CST group were small and did not give rise to complaint in all but

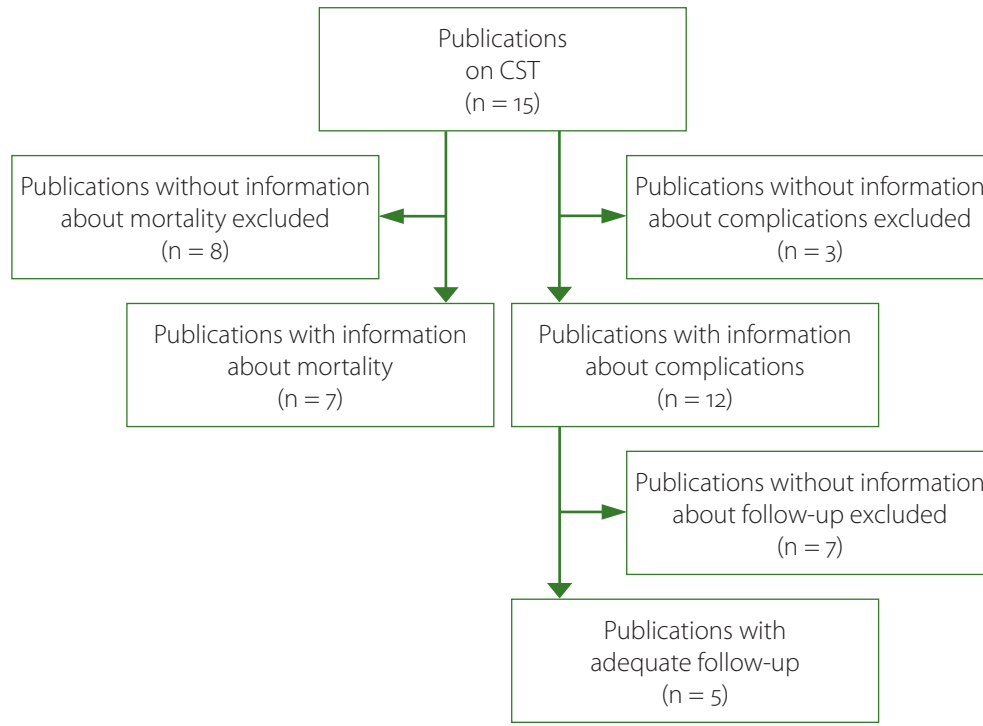


Figure 2 Flow-chart of publications on the “components separation technique” (CST) used for meta-analysis.

two of the patients.<sup>5</sup> It was concluded that, although reherniation rate is common after both procedures the CST should be preferred over prosthetic repair because of the high risk of wound complications with subsequent prosthesis infection.

Fourteen retrospective series including 460 patients were published. The mean MINORS-index was 7 (range 3-8).<sup>8,10,13-24</sup> The retrospective studies were pooled with the 19 patients in the above RCT, give a total of 479 patients.

In-hospital mortality was mentioned in seven series including a total of 248 patients, three of whom died in the post-operative period.<sup>5,10,16-18,22,23</sup> Wound complications were reported in 12 series including 354 patients (Table 1).<sup>5,10,13-15,17,18,20-24</sup> Wound complications were found in 85 of the 354 patients 23.8% (95% c.i. 18.3 to 29.8%) (Figure 3). Wound infection was the most common complication found in 18.9% (95% c.i. 14.9 to 23.2%), seroma in 2.4% (95% c.i. 1.0 to 4.2%), hematoma in 2.4% (95% c.i. 1.0 to 4.2%) and skin necrosis in 1.5% (95% c.i. 0.5 to 3.1%).

Table 1 “Components Separation Technique”. Study characteristics, wound complications and recurrence rates. The publications marked with \* are used for analysis of reherniation.

Reference	Year	MINORS-index	Patients No	Size defect L x W (cm)	Wound complications No (%)	Recurrence No (%)	Follow-up Mean (range) (months)
Dibello et al. <sup>22</sup>	1996	5	35	Not reported	5 (14%)	3 (9%)	22 (1-43)
Shestak et al. <sup>18</sup> *	2000	8	22	7-15 x 12-25	3 (14%)	1 (5%)	52 (44-84)
Cohen et al. <sup>14</sup> *	2001	8	24	20-30 x 15-27	2 (8%)	1 (4%)	? (12-36)
Ewart et al. <sup>13</sup>	2001	3	11	Not reported	3 (27%)	1 (10%)	10 (1-60)
de Vries Reilingh et al. <sup>10</sup> *	2003	8	43	18 x 13	14 (32%)	13 (28%)	15.6 (12-30)
Szczerba et al. <sup>20</sup>	2003	8	11	Not reported	2 (18%)	1 (10%)	24 (6-54)
Ennis et al. <sup>15</sup>	2003	5	10	Not reported	1 (10%)	1 (10%)	26.5 (1-53)
Lowe et al. <sup>17</sup>	2003	7	30	Not reported	6 (20%)	3 (10%)	9.5 (1-26)
Giroto et al. <sup>24</sup>	2003	5	96	Not reported	25 (26%)	21 (22%)	Not reported
Vargo et al. <sup>21</sup>	2004	8	27	Not reported	10 (37%)	2 (7%)	? (6-27)
Van Geffen et al. <sup>23</sup> *	2005	7	26	267 cm <sup>2</sup>	5 (19%)	2 (8%)	? (13-78)
de Vries Reilingh et al. <sup>5</sup> *	2007	23	19	25 x 15	9 (47%)	10 (53%)	36

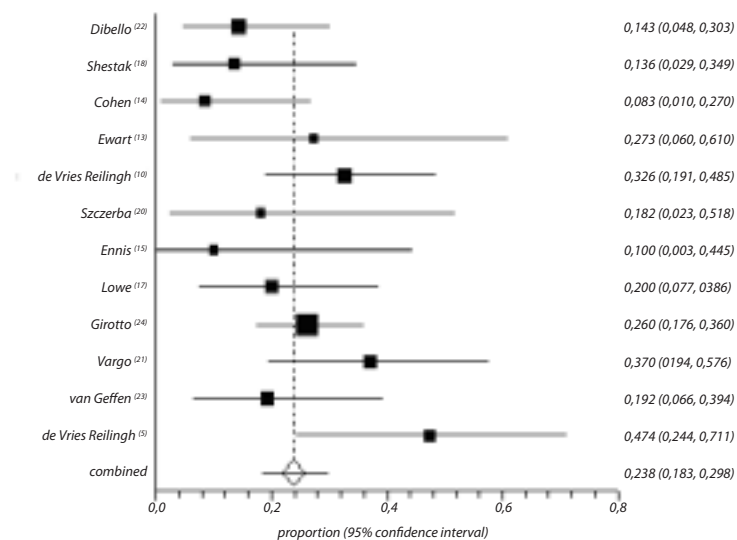


Figure 3 *Meta-analysis plot (random-effects model) of proportion of wound complications in patients treated with the CST. Proportions are shown with 95% confidence intervals.*

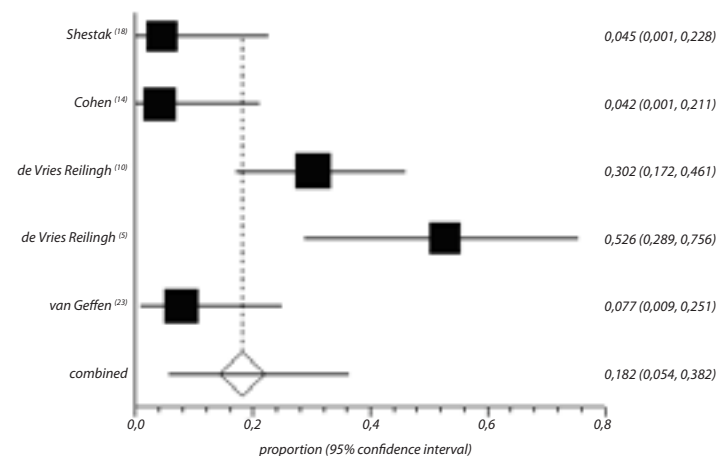


Figure 4 *Meta-analysis plot (random-effects model) of proportion of reherniations in patients treated with the CST. Proportions are shown with 95% confidence intervals.*

A follow-up period of at least 1 year after operation was noted in five series including 134 patients, 27 patients 18.2% (95% c.i. 5.4 to 36.2%) had a recurrent hernia (Table 1 (publications marked with \*) and Figure 4).<sup>5,10,14,18,23</sup>

### Rectus sheath techniques

Several techniques have been described, using the anterior and posterior rectus sheath to bridge the fascial gap. In 1979, da Silva et al. described a technique to repair midline incisional hernias by using both the anterior and posterior rectus sheaths to bridge the fascial gap (Figure 5).<sup>25</sup>

Figure 5

Da Silva Technique

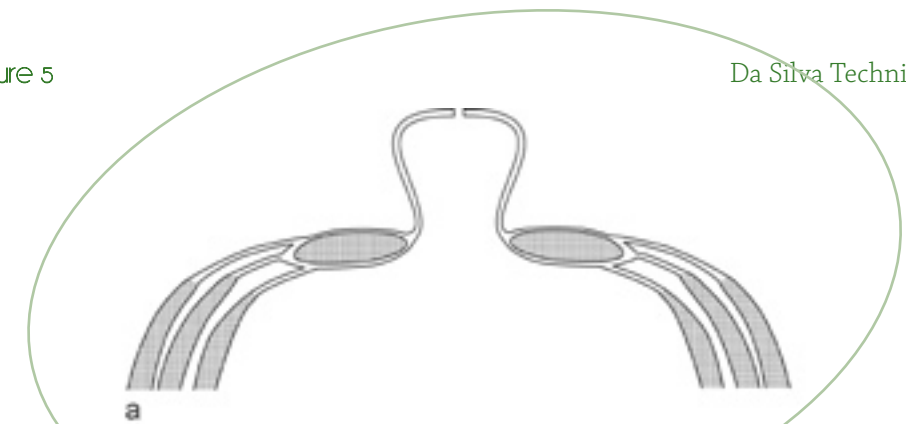


Figure 5a *After opening the abdomen, the bowel and other viscera are dissected free from the ventral abdominal wall. The skin and subcutaneous fat are dissected free from the anterior rectal sheath.*

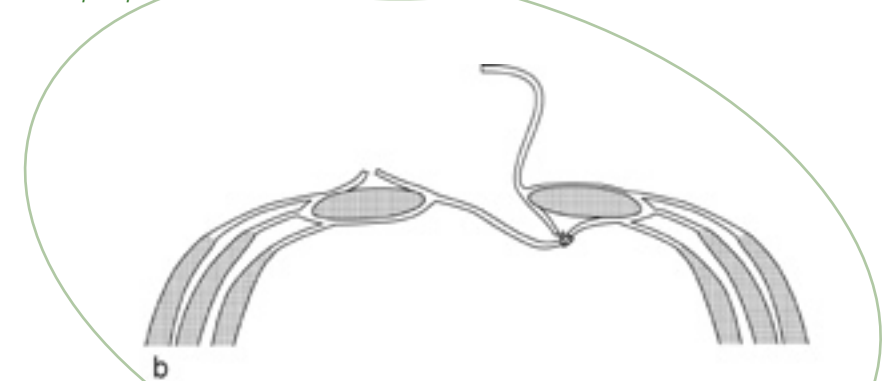


Figure 5b *The right anterior rectus sheath is incised in midline of the right rectus muscle and mobilized to the left. The left posterior rectus sheath is incised in the midline of the left rectus muscle and mobilized to the right.*



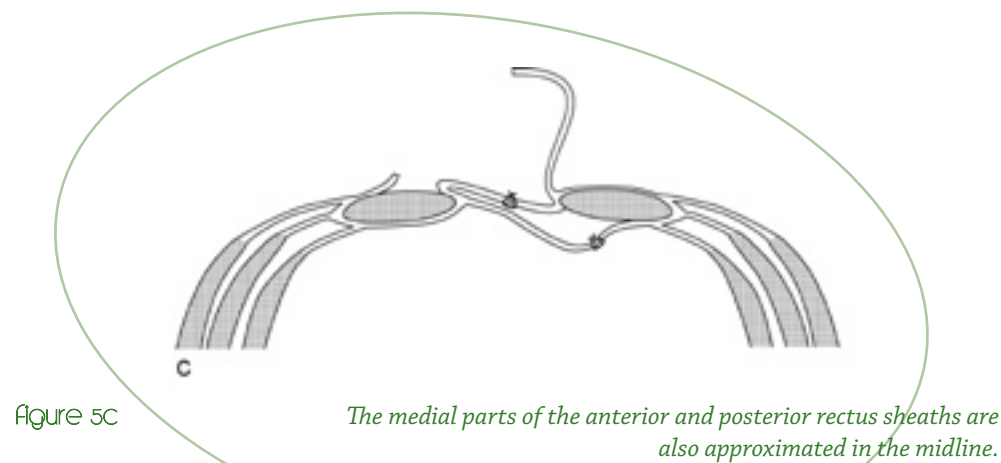


Figure 5c

*The medial parts of the anterior and posterior rectus sheaths are also approximated in the midline.*

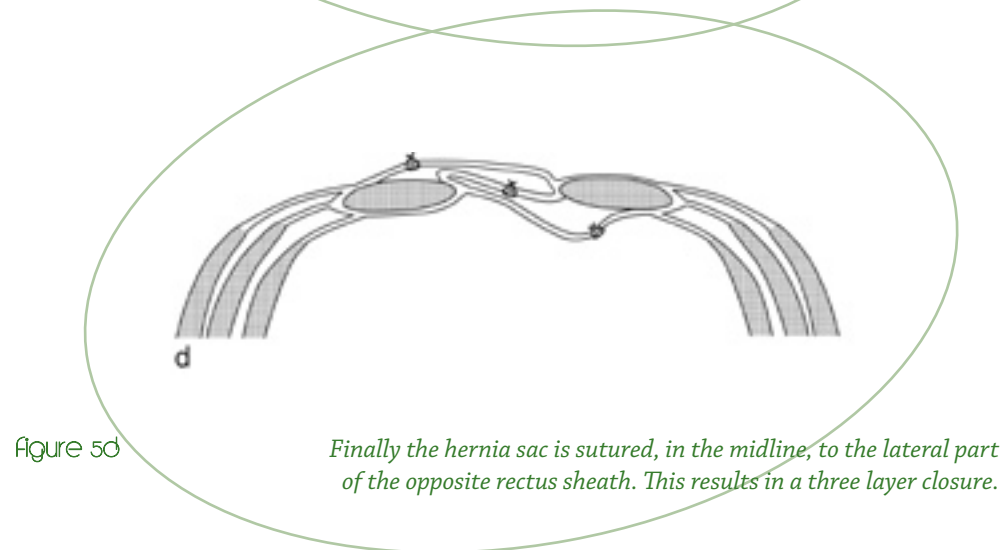


Figure 5d

*Finally the hernia sac is sutured, in the midline, to the lateral part of the opposite rectus sheath. This results in a three layer closure.*

Two series report the results of reconstruction using this technique. The MINORS-index of both publications is 3 (Table 2).<sup>26,27</sup> These publications were not suitable for summary statistic analysis. In a series of 125 patients, with a midline hernia with a mean size of 6.7 cm, da Silva et al. reported no mortality and wound infections in 5%.<sup>26</sup> Recurrent hernia was found in less than 3%, but the duration of follow-up was not stated.<sup>26</sup> Hope et al. reported a mortality rate of 7% in 30 patients; the size of the hernia is not stated. Six patients (20%) had wound complications and no recurrences were reported after a follow-up of 1- 4.5 years.<sup>27</sup>

Table 2

Da Silva technique. Study characteristics, wound complications and recurrence rates.

Reference	Year	MINORS-index	Patients No	Wound complications No (%)	Recurrence No (%)	Follow-up Mean (range) (months)
Hope et al. <sup>27</sup>	1985	3	30	6 (20%)	0 (0%)	30 (12-54)
Da Silva et al. <sup>26</sup>	1991	3	125	6 (5%)	? (<3%)	60 (?)

### Comment

Several techniques have been advocated for the repair of midline abdominal wall hernias using local tissue transfer. Basically there are two methods; CST and techniques using reflected flaps of the anterior and the posterior rectus sheath of the rectus abdominis muscle.

The CST is useful technique for large midline abdominal hernias. It is often complicated by wound healing disturbances and reherniation, and so can only be advocated when prosthetic material is contraindicated. Wound complications are reported in about a quarter of patients. This is explained by the very large wound surface, averaging 700 cm<sup>2</sup>, which is created by mobilizing the skin and the subcutaneous fascia from the ventral abdominal wall muscles, in combination with transection of the peri-umbilical epigastric perforating arteries, thus compromising the blood supply of the skin.<sup>28</sup> Transection of the external oblique muscle and mobilization from the underlying internal oblique muscle further enlarges the wound surface. These very large wounds are predisposed to seroma and hematoma formation. Skin necrosis may occur because the blood supply to the ventral abdominal skin is insufficient especially when the blood supply via the intercostal, superficial circumflex iliac and external pudendal arteries is compromised owing to previous transverse or subcostal incisions.<sup>28</sup> Seroma and hematoma formation, the compromised blood supply of the skin in concert with long operations, sometimes performed in a contaminated field, predispose to the development of wound infections and these were found in about 20% of patients.<sup>5</sup> Because all but one of the series are retrospective and the method of wound surveillance and follow-up are mentioned in only three studies, the overall complication rate is probably underestimated.<sup>5,10,23</sup> To diminish wound complications modifications have been described, that save the blood supply via the peri-umbilical epigastric perforators and reduce the wound surface.<sup>10,11,29</sup>

The rate of reherniation after CST is generally about 18% after a relatively short follow-up of at least one year. Although, at first sight this seems high, the level has been corroborated in several studies. The estimated risk for the development of an incisional hernia after a laparotomy is 11-20.6% and hernia is significantly more common after wound infection.<sup>30-34</sup> The recurrence rate after simple suture repair of an incisional hernia varies from 31 to 49%.<sup>35</sup> It is remarkable that after CST, which is frequently complicated by wound healing disturbances, reherniation rates of less than 10% have been reported. Reherniation after this procedure is probably underreported because of short and incomplete follow-up. When attempting to update the results of the published CST studies (those with unclear follow-up), none of the centres that were contacted, was able to give the details of short and long term follow-up.

It is suggested from retrospective series that recurrence rates after prosthetic repair are much lower, varying from 0-10%,<sup>35</sup> but higher recurrence rates have been reported in a recently published RCT in which prosthetic material was used as an underlay to support a primary suture repair of incisional hernia. Luijendijk et al. and Burger et al. respectively reported recurrence rates of 24% and 32% after prosthetic repair of small ventral hernias; follow-up was 3 and 7 years respectively.<sup>1,2</sup> Comparing light weight polypropylene mesh versus heavy weight polypropylene mesh, Conze et al. noted recurrence rates of 7 and 17% respectively after a follow-up of 12-24 months.<sup>36</sup>

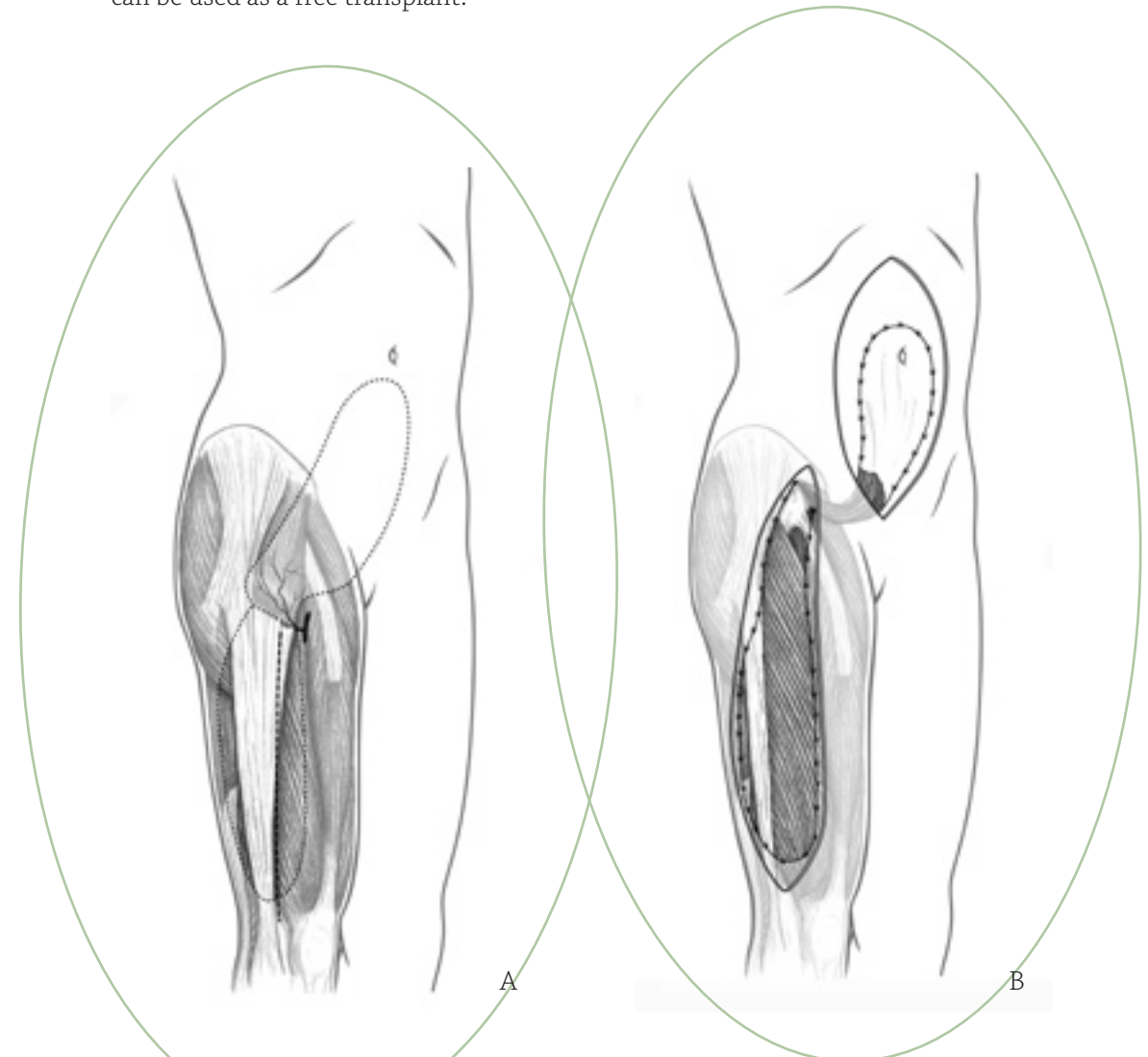
Only two studies on the da Silva technique appear in the literature after 1979.<sup>26,27</sup> The results are remarkably good. Both studies had a MINORS-index of 3 (of 16 points). As in CST, mobilization of the rectus sheath creates a large wound surface and devascularize the fascia. The anterior rectus sheath is used as a fascial transplant similar to the application of free fascia lata graft. (see below). Although a large wound is created accompanied by wound infection in 20%, the recurrence rate, ranging from 0-3%, is remarkably low. The tension free fascial closure and the relatively small size of the hernias probably contributed to these good results, but the methodological quality of both studies is poor and the duration of follow-up was unclear. Definite conclusions about the suitability of the da Silva technique cannot be drawn.

## autologous grafts

### Free fascia lata grafts

Kirschner introduced the use of fascia lata to bridge fascial defects in 1913.<sup>37</sup> It is the most often used free fascial transplant. At the lateral side of the upper leg the fascia

lata is strong and dense. This part of the fascia whose blood supply is via the tensor fasciae latae muscle that is supplied by the lateral circumflex femoral artery (Figure 6), can be used as a free transplant.



**Figure 6a** *Anatomy and dissection of the Tensor Fasciae Latae. For harvesting the musculo-cutaneous flap, a circumferential incision in the skin is made down to the deep fascia, followed by distal mobilization of fasciae latae from the underlying muscles. The vascular supply by the lateral circumflex femoral artery is isolated and saved.*

**Figure 6b** *Pedicled Tensor Fasciae Latae flap. The tensor fasciae latae is dissected from the iliac crest and can be used as an island pedicled flap. If no skin is required, fascia lata, including the muscle, can be transposed in a similar fashion.*

The fascia lata is a versatile graft that is strong enough to resist intra-abdominal pressure. Its collagen fibres are ideally oriented and resist longitudinal slipping of fibres; fibrils are organized to ensure maximum intermolecular cross-linking. Free fascial grafts remain viable after implantation and angiography has shown that they are revascularized. Gallie and Mesurier found that the fascial implants were enveloped in newly formed vascular tissue within 3 weeks of deployment.<sup>38</sup> In contrast to scar tissue, which responds to physical stress by becoming thin and elongated, fascia lata retains its shape, its parallel orientation of fibrils can be seen on electron micrography.<sup>39</sup>

The anchorage of fascia lata to the adjacent myoaponeurotic tissues around the edges of the defect has proved to be better than that of synthetic prostheses, while the tensile strength of the autologous grafts remains constant for at least 1 year after implantation.<sup>40</sup> The grafts are well accepted by the host and fully incorporated into the fibrocollagenous tissue without eliciting a foreign body response. Stimulation of synthesis and net deposition of collagen is yet another advantage.<sup>39</sup>

Harvesting of fascia lata grafts is done via a longitudinal incision at the lateral side of the upper leg. The fascia lata is dissected free from the underlying muscles, excised and the fascial defect is left open. If possible, the posterior condensation of the ilio-tibial tract is preserved to minimize the risk of lateral knee instability (Figure 6).

Fascia lata grafts or myo-fascial flaps inevitably cause a large wound. Donor site morbidity is reported in two series. Williams et al. reported wound complications at the donor site in two of 12 patients.<sup>41</sup> Disa et al. reported complications at the donor site in four of 32 patients: one hematoma, two seromas and one wound dehiscence.<sup>42</sup> No knee instability and other functional deficits were reported.<sup>42</sup>

Four series describe the application of free fascia lata grafts to bridge fascial defects. The median MINORS-index of the publications was of 5.5 (range 3-6) (Table 3).<sup>19,24,41,42</sup>

Williams et al, Disa et al. and Sukkar et al. bridged fascial defects in a total of 48 patients.<sup>19,41,42</sup> The post-operative course was complicated in 18 patients. Abdominal wound complications were mentioned in two series. Williams et al. reported 5 complications in 12 patients: wound dehiscence in two, graft breakdown in two and recurrent small bowel fistula in one patient.<sup>41</sup> Disa et al. reported 13 complications in 32 patients: cellulitis in 3, seroma in 2, skin dehiscence in 7 patients and small bowel obstruction in one. No grafts were lost.<sup>42</sup> Recurrent hernias occurred in 2 of the 12 patients in the

Table 3 Fascia lata graft. Study characteristics, wound complications and recurrence rates.

Reference	Year	MINORS-index	Patients No	Wound complications		Recurrence No (%)	Follow-up Mean (range) (months)
				No (%)	Abdomen		
Williams et al. <sup>41</sup>	1998	6	12	2 (17%)	5 (41%)	2 (17%)	29.2 (?)
Disa et al. <sup>42</sup>	1998	6	32	4 (12.5%)	13 (41%)	3 (9%)	27 (3-106)
Sukkar et al. <sup>19</sup>	2001	3	4	Not reported	Not reported	1 (25%)	24 (?)
Giroto et al. <sup>24</sup>	2003	5	78	Not reported	33 (42%)	23 (29%)	? (>6)

series of Williams et al, after a mean follow-up of 29 months; in 3 of the 32 patients in the series of Disa et al, after a mean follow-up of 27 months and in 1 of the four patients of Sukkar et al. after a mean follow-up of 24 months.<sup>19,41,42</sup>

Giroto et al. combined CST and free fascia lata grafts to repair very large, contaminated abdominal wall defects in 78 patients.<sup>24</sup> Post-operative complications were not specified, but wound infections occurred in 32 patients (41%). Reherniation occurred in 29% of the patients after a follow-up of at least six months (Table 3).<sup>24</sup>

### Autodermal grafts

Loewe first described the use of full thickness skin as a fascial substitute to bridge fascial defects in hernia repair in 1913.<sup>43</sup>

The surplus of skin overlying the hernia sac is excised. Several techniques have been described for preparation of the full thickness skin graft, before its implantation. Loewe removed only the subcutaneous layer and implanted the graft with the dermis facing the intra-abdominal viscera.<sup>43</sup> Reith et al. also implanted the graft up-side-down after perforating the skin.<sup>44</sup> Kranich et al. and Korenkov et al. placed the graft in boiling normal saline for 5 seconds and removed the epidermis with a scalpel before implantation.<sup>45-47</sup> Kranich et al. implanted the graft up-side-down, after perforating the skin.<sup>47</sup> Korenkov et al. disinfected the graft in 96% Ethanol for 3 minutes, after removing the epidermal layer. The graft was rinsed in normal saline and implanted as an onlay support on the primary closed fascia.<sup>46</sup>

Three publications report the results of abdominal wall repair using dermal grafts.<sup>44,46,47</sup>

The mean MINORS-index of the publications was of 5.7 (range 3-10) (Table 4). Kranich et al. repaired ventral hernias in 65 patients and bridged the fascial gap with an autodermal graft. Fourteen patients (22%) had post-operative complications. Recurrences developed in 5 patients (7.5%) after a mean follow-up of 55 (range 6-147) months.<sup>47</sup> Reith et al. found post-operative complications in 20% of 145 patients: 11% had a seroma, 6.2% an abscess and 2.4% a subcutaneous fistula. The recurrence rate was 3.4% after a mean follow-up of 55 (range 12-94) months.<sup>44</sup> Korenkov et al. using the autodermal graft as an onlay support, after primary closure of the fascia in 50 patients, noted 11 post-operative wound complications (22%). The recurrence rate was 14% after 12 months.<sup>46</sup>

Table 4

Autodermal graft. Study characteristics, wound complications and recurrence rates.

Reference	Year	MINORS-index	Patients No	Wound complications No (%)	Recurrence No (%)	Follow-up Mean (range) (months)
Kranich et al. <sup>47</sup>	1990	3	65	14 (22%)	5 (7.6%)	54.6 (6-147)
Reith et al. <sup>44</sup>	1994	4	145	29 (20%)	5 (3.4%)	55 (12-94)
Korenkov et al. <sup>46</sup>	2002	10	50	11 (22%)	7 (14%)	12 (?)

### Comment

Transplantation of fascial or full thickness skin grafts to bridge the fascial gap is attractive, but clinical experience is limited.

The fascia lata is a strong and versatile graft. Fast revascularization and preservation of its physical properties after implantation, make it a nearly ideal fascial substitute. Harvesting is easy and donor site morbidity, being 13-17%, is acceptable. The results of clinical studies support the preclinical data showing that the graft remains viable and retains its physical properties after implantation. Although the wound complication rate of about 40% is high, no graft was lost and the reherniation rate was similar of that of CST.<sup>24,41,42</sup> Bulging, a common complaint after reconstruction of the abdominal wall with myocutaneous flaps was not reported.

Autodermal grafts have been used as a fascial substitute in several clinical studies. They are almost always available and harvesting does not increase morbidity, as the surplus of skin is excised anyway. The wound complication rate of about 20% which is similar to that of other methods. No complications due to outgrowth of skin adnexa were reported. The rate of reherniation after autodermal grafting is low ranging from 3.4-14%.<sup>46,47</sup> In contrast, collagen based prostheses, that are resorbed within one year result in progressive bulging of the abdominal wall, this complication was not reported in the present series of autodermal grafts.<sup>49</sup>

In conclusion, reconstruction with free fascia lata graft and autodermal grafts yields good results, although there must be interpreted with care because of the rather poor quality of the studies.

## pedicled or free vascularized flaps

The two major regional pedicled flaps used to repair lower abdominal wall hernias are the tensor fasciae latae and the rectus femoris muscle flap. For reconstructions in the upper abdomen, free vascularised flaps such as the tensor fasciae latae myo-fascial flap or the latissimus dorsi flap can be used.

### Pedicled and free vascularized tensor fasciae latae flap

Wangensteen first described the use of pedicled tensor fasciae latae (p-TFL) flap in 1934.<sup>49</sup> This flap can be used only for lower abdominal wall defects, owing to the limited length of its pedicle. The p-TFL flap is mobilized in continuity with the tensor fasciae latae muscle and pedicled on its vascular supply. After dissection from the iliac crest, the flap can be rotated on its vascular pedicle or used as a free vascularised flap (Figure 6).

It is mostly used for hernias that are difficult to treat, in a contaminated environment, as a myofascial or myo-fascial-cutaneous flap. The series in literature are mainly descriptive and small. Three series totalling 15 patients with ventral hernias repaired with a p-TFL flap have been reported in literature.<sup>41,50,51</sup> The MINORS-index of these studies was 6, 4 and 1 respectively (Table 5). The method of follow-up was specified in none.

Williams et al. reconstructed abdominal wall defects in 9 patients with a p-TFL flap.<sup>41</sup> In 5 patients there was a contaminated or infected environment. Three flaps needed revision, in two because more than 50% of the flap had become necrotic, and one because of distal tip necrosis. There were no other major complications and no recurrent hernias were observed after a mean follow-up of 21 months. Harpf et al. reconstructed abdominal wall defects in 4 patients.<sup>51</sup> After a follow-up of more than 11 months, none of the patients had a reherniation. Gruen et al. reported two patients in whom an abdominal wall defect was repaired with a p-TFL flap.<sup>50</sup> No major complication or recurrent hernia developed during follow-up of 6 and 11 months. Depuydt et al. reported three patients in whom a p-TFL flap was used to cover an infected mesh.<sup>52</sup> All procedures were successful and complication was stated.

The reach of the p-TFL limits it to the infra-umbilical space. To reconstruct defects in the upper abdomen, free vascularized tensor fasciae latae (f-TFL) can be used, first described by Hill et al.<sup>53</sup> The results of repair of ventral hernias with f-TFL have been described in four retrospective case series containing a total of 20 patients (Table 6).<sup>41,54-56</sup>

Table 5 Pedicled fasciae latae flap. Study characteristics, wound complications and recurrence rates.

Reference	Year	MINORS-index	Patients No	Wound complications		Recurrence No (%)	Follow-up Mean (range) (months)
				No (%)	Abdomen		
Williams et al. <sup>41</sup>	1998	6	9	1 (11%)	3 (33%)	0	21.3 (?)
Harpf et al. <sup>51</sup>	1997	4	4	Not reported	Not reported	0	17 (11-20)
Gruen et al. <sup>50</sup>	1998	1	2	Not reported	0 (0%)	0	? (6-11)



Table 6 Free vascularized fasciae latae flap. Study characteristics, wound complications and recurrence rates.

Reference	Year	MINORS- index	Patients No	Wound complications		Recurrence		Follow-up Mean (range) (months)
				No (%)	Abdomen	No (%)	Abdomen	
Penington et al. <sup>55</sup>	1996	4	4	Not reported	2 (50%)	Not reported	Not reported	
Williams et al. <sup>41</sup>	1998	6	6	2 (33%)	2 (33%)	2 (33%)	20.2 (?)	
Chevray et al. <sup>54</sup>	2003	3	3	Not reported	Not reported	0	? (4-8)	
Kuo et al. <sup>56</sup>	2004	10	7	Not reported	3 (43%)	0	12 (?)	

These studies had a MINORS-index ranging from 3 to 10. Follow-up ranged from 4-20 months, although the method of follow-up was not specified. Donor-site morbidity was only reported by Williams in 50%.<sup>41</sup> Partial flap necrosis, which needed surgical debridement, occurred in 5 of the 20 patients, two of whom also had flap-fascia dehiscence. Three other patients had a wound infection and one patient had a successful intervention for venous obstruction. Reherniation was found in two patients and bulging of the flap in four patients (Table 6).<sup>41,54-56</sup>

Rectus femoris flap

The rectus femoris myocutaneous flap is a relatively long but narrow flap that can be used to repair defects in the lower abdomen. It is pedicled on the lateral circumflex femoral artery and tunnelled subcutaneously to the lower abdomen. Four publications report the results of reconstruction of an abdominal wall defect using such a flap: one case series and three case reports including altogether a total of 11 patients (Table 7).<sup>57-60</sup> The method of long term follow-up is not specified. Caulfield et al. reconstructed 13 abdominal wall defects using a pedicled rectus femoris flap;<sup>58</sup> seven patients had unilateral and 6 had bilateral procedures. Only two had major complications: a hematoma in 1 patient and loss of a split skin graft at the donor site in another. There were no recurrences after a follow-up of 3-18 months. Using the rectus femoris muscle led to a significant loss of muscle strength during bending the knee. Two case reports reported good results without complications.<sup>59,60</sup> In the third case report, reconstruction was complicated by an enterocutaneous fistula.<sup>57</sup>

Latissimus dorsi flap

The latissimus dorsi muscle can be used as a pedicled or free flap. It is widely used for breast reconstruction after ablative surgery. The free latissimus dorsi flap can also be used for reconstruction of abdominal wall defects.<sup>61</sup> Three case series have been published in literature including a total of 13 patients (Table 8).<sup>51,61,62</sup> In none of the studies is the method of long term follow-up specified. Houston et al. used the latissimus dorsi flap in 6 patients, without post-operative complications, loss of flap or recurrent hernia.<sup>61</sup> Harpf et al. used a latissimus dorsi flap in 3 patients. Skin necrosis at the donor site occurred in one, but no patient developed a recurrent hernia.<sup>51</sup> Ninkovic et al. used a free innervated latissimus dorsi flap in 4 patients.<sup>62</sup> A donor site seroma occurred in one but again, no patient developed a recurrent hernia.

Table 7 Rectus femoris flap. Study characteristics, wound complications and recurrence rates.  
All publications are case reports and MINORS-index are not applicable.

Reference	Year	MINORS-index	Patients No	Wound complications No (%)	Recurrence No (%)	Follow-up Mean (range) (months)
Donor-site Abdomen						
Freedman et al. <sup>59</sup>	1990	Not applicable	1	Not reported	0	1
Brown et al. <sup>57</sup>	1993	Not applicable	2	Not reported	1 (50%)	Not reported
Caulfield et al. <sup>58</sup>	1994	Not applicable	7	1 (14%)	1 (14%)	? (3-18)
Koshima et al. <sup>60</sup>	1999	Not applicable	1	0 (0%)	0 (0%)	54

Table 8 Latissimus dorsi flap. Study characteristics, wound complications and recurrence rates.  
All publications are case reports and MINORS-index are not applicable.

Reference	Year	MINORS-index	Patients No	Wound complications No (%)	Recurrence No (%)	Follow-up Mean (range) (months)
Donor-site Abdomen						
Houston et al. <sup>61</sup>	1988	Not applicable	6	0 (0%)	0	? (7-66)
Harpf et al. <sup>51</sup>	1997	Not applicable	3	1 (33%)	Not reported	? (9-37)
Ninkovic et al. <sup>62</sup>	1998	Not applicable	4	1 (25%)	1 (25%)	21 (?)

### Comment

Pedicled or free vascularised flaps are used as methods last resort because they are complex, take a long time and create large donor site defects. The exact place of these procedures in the treatment of abdominal wall defects is not clear, as information in literature is scarce and fragmented. In general, they should be reserved for patients in whom local tissue transfer is impossible and free tissue grafting is contraindicated. Reconstruction in poorly vascularised tissue, such as in irradiated areas is a further indication.

The TFL flap is the most often used and most appropriate flap for abdominal wall reconstruction. It combines well vascularised tissue with a strong fascia that can resist intra-abdominal pressure. When skin defects are present, a combined myo-fascio-cutaneous flap can be used. The application of muscular flaps alone (without any fascial component) for abdominal wall repair is not advised, as the denervated muscle will not resist intra-abdominal pressure, and results in bulging of the abdominal wall in the long term. In the light of this, surgeons try to restore the abdominal wall defect by using an innervated flap, hoping to restore motility and prevent bulging.<sup>62</sup> Ninkovic et al. has shown that reconstruction using a free innervated latissimus dorsi flap and intensive post-operative muscle training offers enough contractile capacity and strength to replace missing abdominal wall muscles.<sup>62</sup>

Because the published series on myo-fascio-cutaneous flaps are small and not well documented and because they contain selected patients, a definite assessment of post-operative morbidity and recurrence rates cannot be made. The morbidity rate is up to 50% both at the donor and the recipient sites. The most important complication is (partial) flap necrosis which can be expected in 10-50% of patients.

### discussion

Autologous repair of abdominal wall hernias should be reserved for patients in whom prosthetic repair is contraindicated as the rate of reherniation is similar to that found after open suture repair; there is significantly less recurrence if prosthetic materials are used.

Contamination in the operative field is the most important reason for reconstruction of the abdominal wall with autologous material. Under these circumstances the risk of prosthetic infection is increased and often results in chronic infection with sinus formation or loss of the prosthesis.

In general, prosthetic repair should be preferred over autologous repair. The recurrence rate of primary closure of the fascia is unacceptably high.<sup>1,2,35</sup> and for hernias that cannot be closed primarily, bridging the fascial gap with polypropylene mesh is considered as the 'gold' standard, although clear evidence is lacking.<sup>1,2,35</sup> If prosthetic materials are contraindicated, a fascial gap can be bridged temporarily with resorbable mesh while the conditions improve to allow for delayed repair. In such circumstances autologous repair is an attractive alternative.<sup>14,16,62</sup>

Autologous repair of small midline hernias is best performed with the da Silva technique. Morbidity is low and the recurrence rate is up to 3%. Large abdominal wall hernias up to 30 cm at the waistline can be closed fairly easily with the CST, but the procedure is more complicated, and very large wounds are created. The procedure is accompanied by considerable morbidity. Recurrence rates of 18% after one year are acceptable as similar results are reported in RCT assessing patients with smaller hernias that can closed primarily with prosthetic support.<sup>1,2,36</sup> However information on long term outcome is scarce. In the authors own experience recurrence rates of over 30% after 2-year follow-up can be expected. Most recurrent hernias after CST are small and need no further treatment. Furthermore the results of CST may be improved if the epigastric perforators are spared, to prevent ischemia and necrosis of the midline skin.

If these techniques fail the fascial gap can be bridged by free fascial transplants, autodermal grafts or pedicled or free vascularised myo-fascial-cutaneous flaps. The free fascia lata graft is attractive if the fascial gap cannot be bridged by CST alone. Autodermal grafts are an alternative. Still although reported results are good, they must be interpreted with care as the methodological quality of the studies is poor.

Pedicled or free vascularised flaps should be reserved for the very complex situations in which free grafts cannot be used and reconstruction must be performed with vascularised tissue. These lengthy and complicated procedures are associated with a considerable morbidity at both the donor- and recipients side, re-operations are common.

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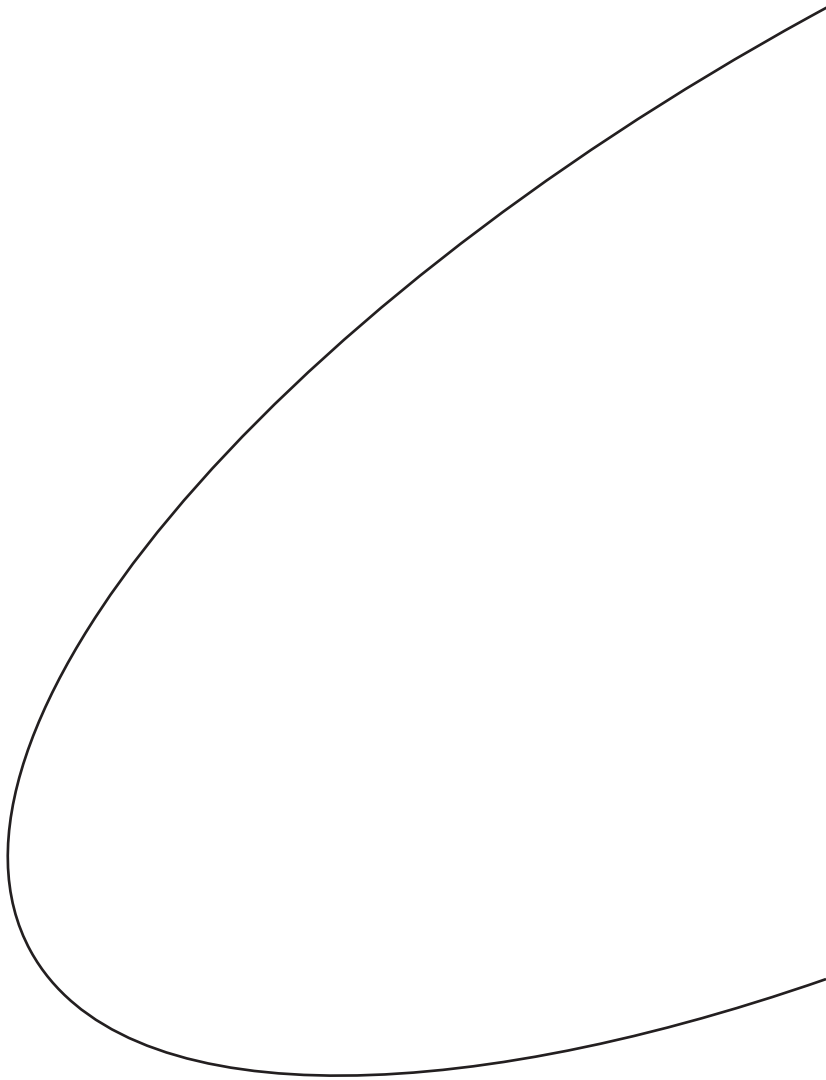
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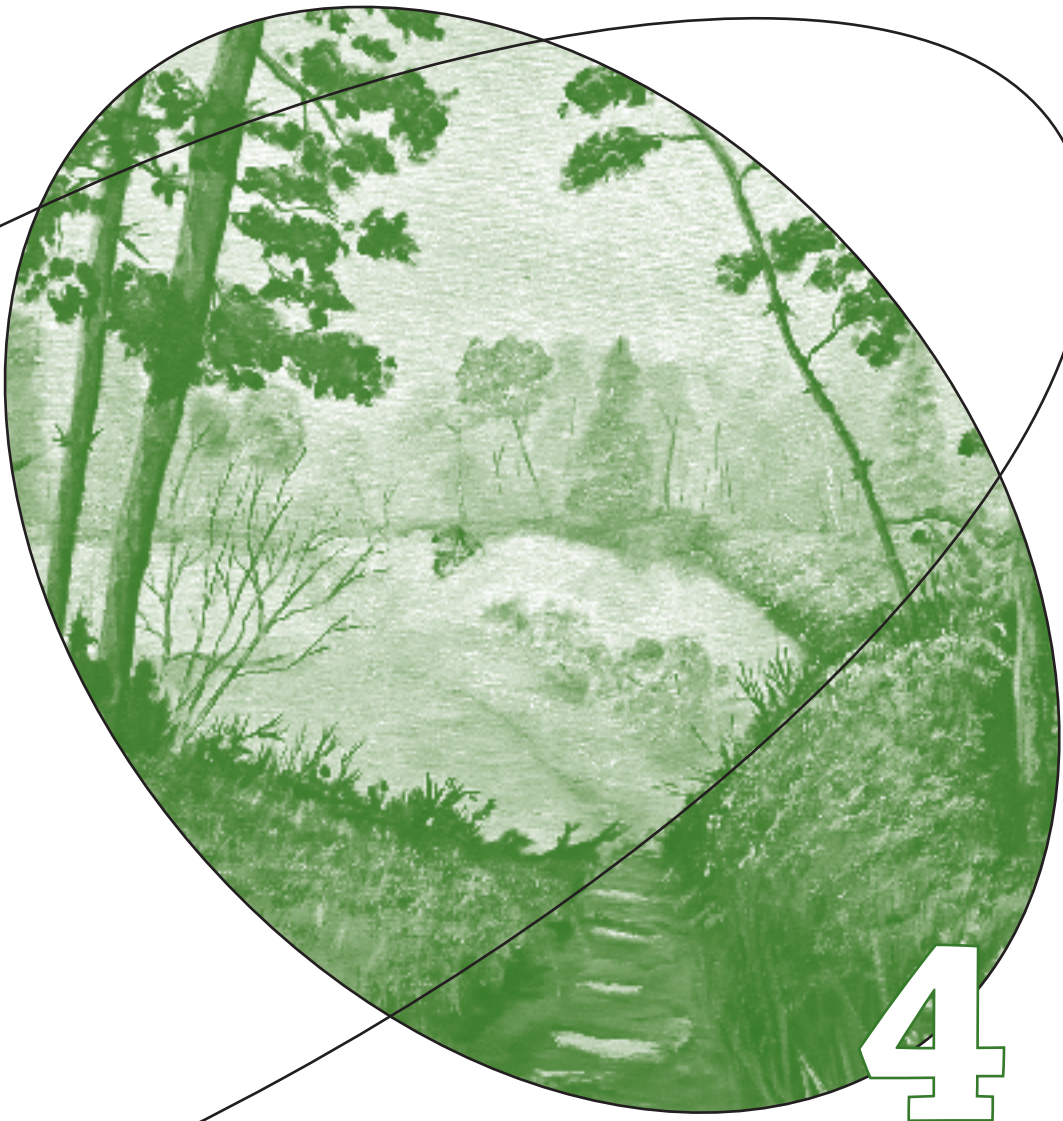
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# repair of giant midline abdominal wall hernias: "components separation technique" versus prosthetic repair

interim analysis of a randomized controlled trial

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## introduction

Reconstruction of giant midline abdominal wall hernias that cannot be closed primarily is a technical challenge to a surgeon. Many surgeons discourage abdominal wall reconstruction because of the technical difficulties, the high morbidity, and the relatively high recurrence rate associated with these procedures. However, many patients with large hernias have invalidating complaints such as bulging of the abdominal wall, chronic wounds, immobility and back pain, necessitating surgical treatment.

The lack of sufficient tissue requires the insertion of prosthetic material or transposition of autologous material to bridge the fascial gap. Reconstruction using pre-peritoneal placed prosthetic material is still the most frequently applied method of reconstruction.<sup>1</sup> The increased risk of infection in case of wound complications is a relative contra-indication against the use of prosthetic materials. Moreover, interposition of either peritoneum or greater omentum between the bowels and the prosthesis is often impossible, which is another reason to avoid the use of prosthetic material.

In 1990 Ramirez, Ruas, and Dellon introduced the “components separation technique” (CST) to bridge the fascial gap without the use of prosthetic material.<sup>2</sup> The technique is based on enlargement of the abdominal wall surface by separation and advancement of the muscular layers. In this way, defects of up to 20 cm at the waistline can be bridged. Retrospective series report promising results, but no prospective study has been published until now.<sup>3-12</sup> It was the aim of this prospective study to compare the results of prosthetic repair with CST in patients with giant abdominal wall hernias that cannot be closed primarily. Primary endpoint of the study was: reherniation, secondary endpoints were operation time and post-operative wound complications. In the present report the results of an interim analysis are presented.

## patients and methods

Adult patients (18-80 years) with an incisional hernia after midline laparotomy with a cranio-caudal length of at least 20 cm, that could not be closed primarily, in whom the repair could be performed under clean or clean-contaminated conditions, and who were not using corticosteroid therapy were asked to participate in the study. Patients with peri-operative gross contamination of the operative field were excluded from the

study. After written informed consent the patients were randomized between CST and prosthetic repair by the datacenter of the Radboud University Nijmegen Medical Center using envelope, the day before operation.

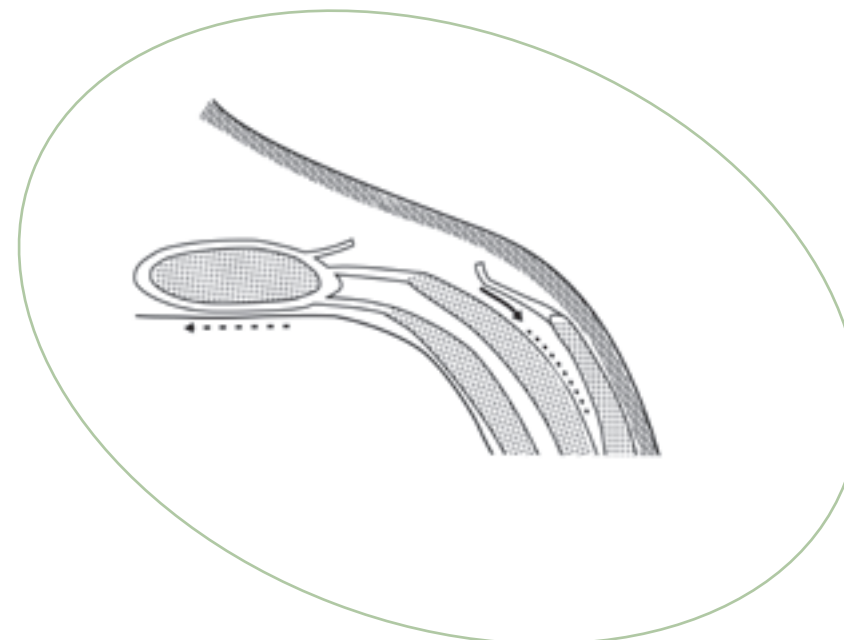
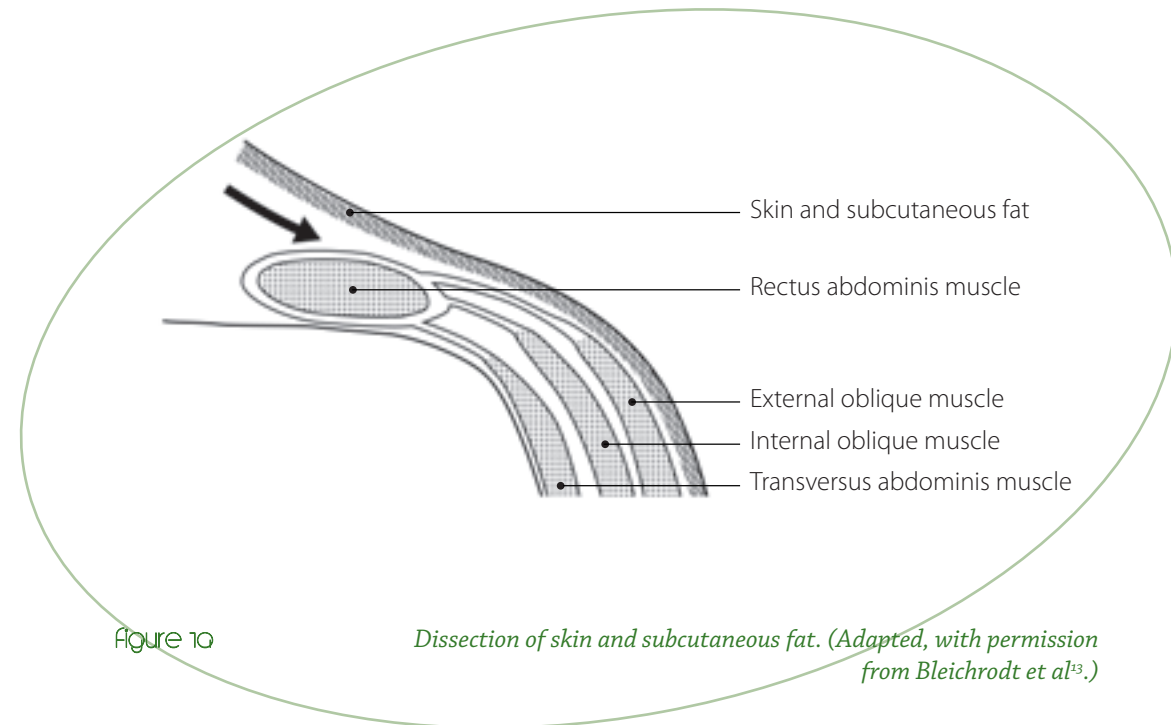
Fully trained abdominal wall surgeons who had done at least five procedures of both techniques before the start of the study, performed the operations. HvG and RPB performed supervision in centers not having this expertise. Before each procedure, a pre-operative chest X-ray was made. Demographic data, co-morbidity (COPD, cardiovascular disease and diabetes), body mass index, condition of the skin, size of the hernia at the time of the operative procedure, kind of anesthesia, operation time, peri-operative blood loss, post-operative ICU stay, analgesia use, complications, hospital stay and follow-up were recorded on a standard form. The study protocol was reviewed and approved by the institutional ethics commissions of all the participating hospitals. All patients gave written informed consent after receiving a thorough explanation of the study.

### Operative technique

Standard thrombosis (Nadroparine 2850 IE) and antibiotic prophylaxis (Cefazoline 3 x 1 grams and Metronidazol 3 x 500 milligrams) were started pre-operatively. After induction of anesthesia (combined general and epidural, if possible) and disinfection of the skin with iodine tincture, adhesive drape was applied on the skin, if possible. The abdomen was entered via a midline laparotomy or at the lateral edge of the graft if the bowels were covered with a split skin graft. Adhesions between the ventral abdominal wall and the intra-abdominal viscera were cut after which the length and width of the defect were measured.

#### "Components Separation Technique" (CST group)

The "components separation technique" was performed as described in detail in former publications.<sup>2,12,13</sup> Briefly: The skin and subcutaneous fat are dissected free from the anterior rectus sheath and the aponeurosis of the external oblique muscle (Figure 1A). The aponeurosis of the external oblique muscle is transected longitudinally about 2 cm lateral from the rectus sheath, including the muscular part that inserts on the thoracic wall, which extends at least 5-7 cm cranially of the costal margin (Figure 1B). The external oblique muscle is separated from the internal oblique muscle, as far laterally as possible (Figure 1B). The posterior rectal sheath is separated from the rectus abdominal muscle, if tension free closure is impossible (Figure 1C). The fascia is closed in the midline with a running polydioxanone suture (PDS-loop, Ethicon, Johnson & Johnson Medical, Norderstedt, Germany) of at least 4 times the length of the incision. The skin is closed over at least two closed suction drains.





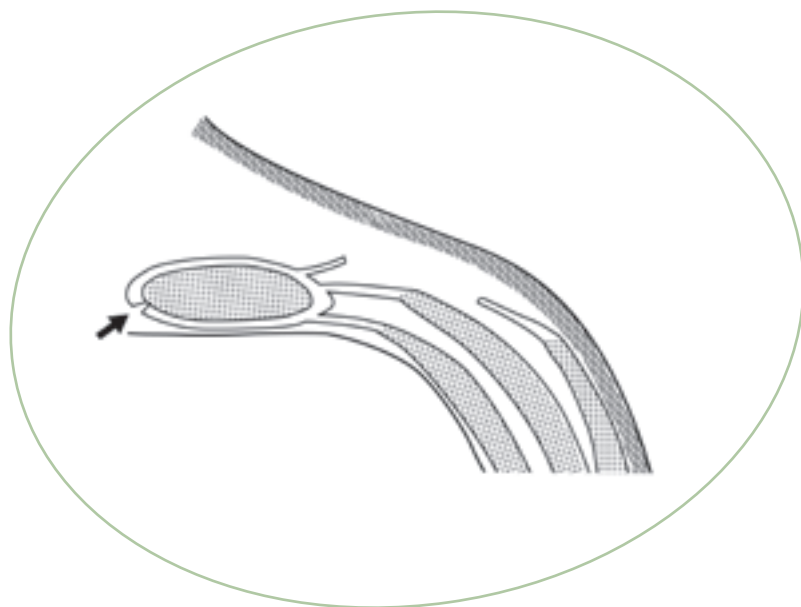


Figure 1C Mobilization of the posterior rectal sheath and closure in the midline.

#### Prosthetic repair (e-PTFE group)

The skin and subcutaneous tissue are mobilized from the underlying fascia of the rectus abdominis muscle. As a consequence all epigastric perforating arteries, supplying the overlying skin, are separated. After adhesiolysis, a 20 x 30 cm, 1.5 mm thick e-PTFE patch (Gore-Tex dual mesh plus with holes, W.L. Gore and associates Inc., Flagstaff, Arizona, USA) is shaped in size and implanted intra-abdominally as underlay with an overlap of at least 4 cm to the aponeurosis, as described elsewhere.<sup>14</sup> The mesh is placed intra-abdominally as an underlay and is sutured under slight tension to the ventral abdominal wall using a double row of interrupted sutures of e-PTFE 1/0 (Gore-Tex 1/0, W.L. Gore and associates Inc.) that passed rectus abdominis muscle. The prosthesis is implanted with the microporous side facing the intra-abdominal viscera and the macroporous side facing the fascia. As a consequence of the large size of the hernias, the fascia could not be closed over the prosthesis in any of the patients in our series. After implantation, the skin is closed over at least two closed suction drains.

#### Postoperative care

Antibiotic prophylaxis, Cefazoline 3 x 1 grams and Metronidazol 3 x 500 milligrams was started pre-operatively and continued, for the first 24 hours post-operatively. All patients have epidural anesthesia if possible. Wounds were inspected on a daily basis

with respect to hematoma, seroma, skin necrosis and wound infection. Hematoma was defined as an accumulation of blood in the operative field for which a surgical intervention (puncture or drainage) was needed; seroma as an accumulation of fluid in the operative field for which an intervention (puncture or drainage) was needed in case of mechanical or physical limitations. Skin edge necrosis was defined as necrotic loss of full thickness skin for which surgical intervention was needed.

The wound was scored on a daily basis according to CDC criteria as follows: grade 1: normal wound, grade 2: erythema and swelling, grade 3: purulent effluent or grade 4: open wound. Drains were removed after 5 days or if production was less than 50 ml/24 hours.

The thorax was examined daily by physical examination and a routine X-ray of the thorax was performed on the second and seventh day after the operation, to detect pneumonia and atelectasis. No specific instructions were given to the patients after operation and patients had no restriction of physical activity except heavy lifting. Follow-up was done in the outpatient clinic at 3, 6, 12, 24 and 36 months after operation. At each visit a physical examination was done to diagnose recurrent hernia. Ultrasonography or Computed Tomography (CT) scanning was performed on indication, especially to detect small recurrences.

#### Statistical analysis

Patients were analyzed as per intention to treat. Hernia recurrence free survival was compared using the Kaplan-Meier methods according to the intention-to-treat principle.

#### Power analysis

Type I and II errors were set to 0.05 and 0.1 respectively. The minimum relevant difference in reherniation between groups was set to 30%, in advantage of CST. Accordingly, a minimum of 84 patients was required (two groups of 42 patients). An interim analysis was planned to evaluate the results of the trial after inclusion of 40 patients.

Differences between groups were analyzed using the Fisher-exact test for demographic data, pre-operative and peri-operative data, wound complications, reoperation and reherniation (Table 1).

Table 1 Study characteristic of patients with prosthetic repair or “components separation technique”. (BMI: body mass index, ICU: intensive care unit, OR: operation room, NS = not statistically significant).

Table 1			
		Group I: prosthetic repair	Group II: “Components Separation Technique”
			Significance
Age (mean)		58.7 (range 42-82)	53.9 (range 33-37) (t-test) NS
Gender (women/men)		6/12	6/13 (Fisher exact) NS
BMI		28.7 (range 21.5-39.6)	28.2 (range 23.9-38.7) (t-test) NS
Defect (median) (cm)			
Length		25 (range 20-30)	25 (range 20-33) (t-test) NS
Width		17 (range 9-30)	15 (range 7-25) NS
Skin (n)			
Intact, full thickness		14	12 (t-test) NS
Intact, split skin		4	7 NS
Anesthesia (n)			
General		3	5 (Fisher-exact) NS
Epidural and General		15	14 NS
Operation Time (min)		183 (range 135-254)	113 (range 63-175) (t-test) $P < 0.001$
Blood loss (ml)		420 (range 100-900)	289 (range 50-1000) (t-test) NS

Table 1 Continued

Table 1 Continued			
		Group I: prosthetic repair	Group II: “Components Separation Technique”
			Significance
ICU Stay			(Mann-Whitney U)
Patients (n)		6	3 NS
Time (days)		2 (range 1-6)	5 (range 1-10) NS
Pulmonary complications (n)			
Pneumonia		2	4 (t-test) NS
Atelectasis		2	1 NS
		0	3 NS
Analgesia			
Epidural (days)		2.4 (range 0-5)	2.4 (range 0-6) (t-test) NS
Morphine (days)		3.3 (range 0-8)	3.6 (range 0-10) NS
Wound Complications (n)			
Hematoma		1	1 (Fisher-exact) NS
Seroma		7	4 NS
Skin Necrosis		3	2 NS
Wound Infection		2	3 NS
Infected Mesh (n)		7	0
Re-operation (in operation room) for wound complications (n)		7	2 (t-test) $P = 0.05$
Recurrence (n)		11	10 NS

## results

Between November 1999 and June 2001, 39 patients were included in the study and were operated on by one of 5 surgeons. Two patients were excluded from the study because of gross contamination during operation. **Nineteen patients, 6 women and 13 men**, were randomized in the CST group: reconstruction using the "components separation technique" (CST). The mean age of these 19 patients was 53.9 years (range 33-73). Eighteen patients, 6 women and 12 men, were randomized in the e-PTFE group (prosthetic repair). Their mean age was 58.7 years (range 42-82 years).

In the CST group, closure of the fascia was accomplished in 18 of the 19 patients (Figure 2). In one patient the abdominal wall hernia was too large and had to be repaired using a combination of the CST and prosthetic repair. In the e-PTFE group the procedure was successful in 17 of the 18 patients. In one patient the abdominal wall hernia was too large and was reconstructed using a combination of prosthetic repair and CST. No differences were found between the groups with respect to demographic data (Table 1), co-morbidity, length and width of the defect, skin coverage, anesthesia, blood loss and ICU stay (Table 1). All operations were performed without major intra-operative complications, except for the two excluded patients with gross peri-operative contamination. The operation time for prosthetic repair was significantly longer

as compared with the "components separation technique" ( $P < 0.001$ , Fisher exact test (Table 1)). This is mainly due to the time-consuming fixation of the patch to the fascia with a double row of single sutures.

### Postoperative mortality and morbidity

There was no 30-day mortality. Major wound complications were found in 10 of the 19 patients in the CST group: wound infection ( $n = 3$ ), skin necrosis ( $n = 2$ ), hematoma ( $n = 1$ ). **Four patients developed seroma**, these were not associated with aforementioned complications.

Major wound complications were found in 13 of the 18 patients in the e-PTFE group: wound infection ( $n = 2$ ), skin necrosis ( $n = 3$ ), hematoma ( $n = 1$ ). Both wound infection and skin necrosis ultimately resulted in loss of the prosthesis (Table 1). Seven patients developed a seroma. In two of these patients seroma puncture was performed to prevent spontaneous evacuation via the midline wound, this resulted in infection and ultimately in loss of the patch. Seven patches were removed after a median period of 94 days (range 30-262 days). **In the cases where the prosthesis was removed**, the abdominal wall defect was reconstructed using CST.

Pulmonary complications were found in 4 patients in the CST group and 2 in the e-PTFE group (not significant, Fisher exact test (Table 1)).

### Reherniation

Follow-up was complete in all patients.

Four patients in the CST group died before the end of the follow-up period 5, 9, 10 and 12 months after the operation from unrelated causes. Two had a reherniation at the time of death. Of the remaining 15 patients, 8 had a reherniation. Recurrences occurred after a mean period of seven months (range 0.5-12 months). Recurrences were all located in the midline in the upper abdomen and were small. Two patients underwent a reconstruction of their recurrence. One patient in whom the reconstruction was performed with a combination of CST and prosthetic bridging had a recurrent hernia at the edge of the prosthesis (Figure 3).

### Prosthetic Repair

One patient in the e-PTFE group died 6 months after the operation from a unrelated cause. Of the remaining 17 patients, 7 had an infected prosthesis that had to be re-

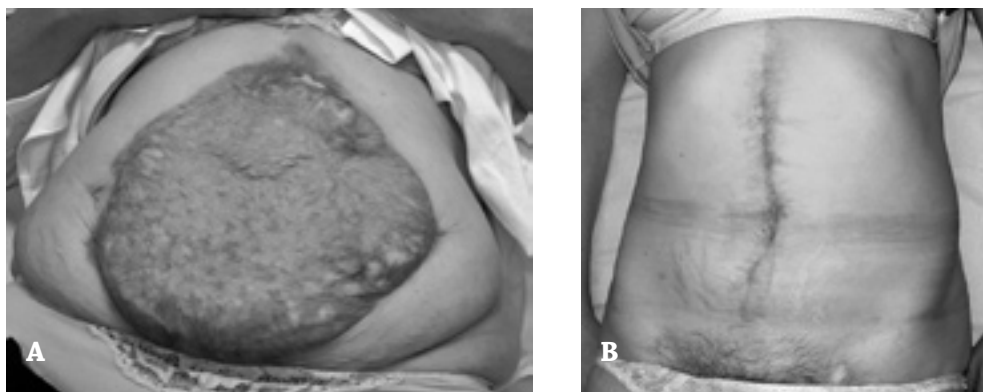
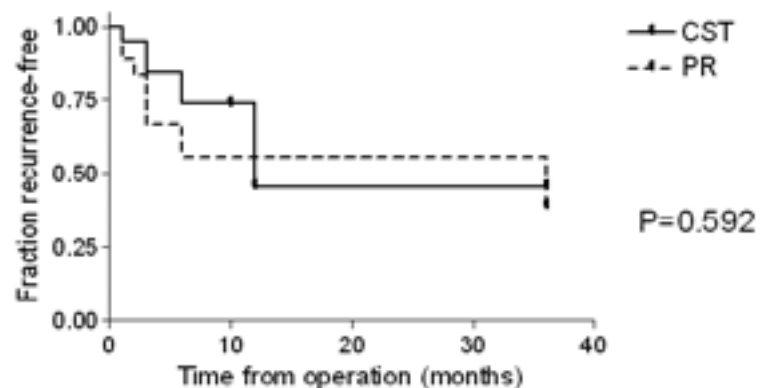


Figure 2a *Pre-operative view of a giant abdominal wall hernia covered with a split skin.*

Figure 2b *Post-operative view of the same abdominal wall after reconstruction using "components separation technique".*

moved. The abdominal wall defect was then reconstructed using CST repair. Four other patients had a small recurrent hernia after prosthetic repair, without complaints. Recurrences occurred after a mean period of 22 months (range 6-36 months). None of these four patients underwent reoperation for their recurrence (Figure 3).



**Figure 3** Kaplan-Meier plot for recurrent hernia after prosthetic repair ( $n = 18$ ) and “components separation technique” ( $n = 19$ ). Seven out of 18 prostheses have been removed in the first 7 months after implantation. Reherniation rates after 36 months are similar in both groups.

## discussion

The present study is the first randomized controlled trial comparing different techniques to repair giant midline hernias and the first prospective trial regarding the “components separation technique”. Although our series is relatively small, the results suggest that repair of giant abdominal wall defects with the “components separation technique” compares favourably with prosthetic repair, because wound infection in patients in whom a prosthetic repair was performed, had major consequences, resulting in removal of the prosthesis in seven, whereas wound infection in patients after CST had only minor consequences.

Disturbed wound healing frequently complicates repair of large abdominal wall hernias. Wound complications such as hematoma, seroma, skin necrosis and infection are reported in 12%-67% of patients after CST<sup>2-5,7-12,16</sup> and in 12%-27% after prosthetic repair. Wound complications are associated with the extensive dissection needed in both procedures, which are often performed after intra-abdominal catastrophes. The risk is further increased by the long duration of the operative procedure and the need to mobilize the skin dividing the epigastric perforating arteries (Figure 4). This endangers the blood supply of the skin, because then it solely depends on the intercostal arteries, which may have been damaged during former operations by introduction of drains, or by stoma construction and other procedures needed in patients with intra-abdominal sepsis.<sup>17-19</sup>

Wound complications in our series were rather frequent. Although they are mentioned in most other publications about CST, the method of follow-up is mentioned in only one other study from our own group.<sup>12</sup>

Loss of the prosthesis may also be associated with the choice of the prosthetic material used. Several prosthetic materials have been developed for hernia repair. In the



**Figure 4** The operation wound after performing a “components separation technique” for abdominal wall reconstruction, showing the large wound surface and the extensive skin dissection needed.

present series only patients with giant and often complex hernias were included. In the majority of these patients the peritoneum or greater omentum was not available to interpose between the prosthesis and the intra-abdominal viscera. Therefore, an e-PTFE dual patch was used to bridge the fascial gap.

The e-PTFE dual patch has significantly better mechanical properties than polypropylene mesh. It is a soft pliable microporous material that causes no mechanical trauma to the viscera. The micropores on both sides of the patch are too small to allow ingrowth of fibrocollagenous tissue, thus preventing fibrous adhesions on the visceral side of the patch. Lack of ingrowth results in insufficient anchorage of the patch to the adjacent fascia, however, and this is a major disadvantage of e-PTFE patches.<sup>14,20,21</sup> The patch should be placed as underlay with an overlap of at least 4 cm and fixed to the aponeurosis with a double row of single sutures.<sup>14</sup>

The e-PTFE patch is prone to infection because of its hydrophobic characteristics. To reduce the infection risk, the e-PTFE patch used is impregnated with silver salts and chlorhexidine, which both have anti-microbial properties and work synergistically.<sup>22</sup> Moreover, antibiotic prophylaxis was given to all patients and adhesive drape was applied to the skin. Nevertheless, 40% of our patients had an early or late infection resulting in removal of the patch. In a recent experimental study in rats with a large abdominal wall defect, it was found that impregnation with silver salts resulted in an aggravated inflammatory response around the patch and an increased reherniation rate.<sup>23</sup> This observation may explain the increased risk for seroma formation, which is associated with prosthetic loss in this study. Some patients (n = 3, 16%) were operated under clean-contaminated condition, which means they had an accidental bowel lesion during adhesiolysis without gross contamination. We suspect that most surgeons still place a prosthetic patch for abdominal wall reconstruction in these situations, which is supported by some small series in literature.<sup>24,25</sup>

In our opinion polypropylene, which is still the most widely used material for hernia repair, is contraindicated because of its propensity for inducing extensive visceral adhesions and occasional fistula formation.<sup>26-28</sup> If large areas of polypropylene mesh are exposed, scar contraction will result in wrinkling of the polypropylene mesh, causing mechanical irritation, which promotes infection and carries the risk of mesh erosion into the skin or the intestine.<sup>29</sup> If the polypropylene mesh cannot be covered with full-thickness skin, chronic infection and sinus formation will ultimately result in loss of the mesh.<sup>27</sup> Therefore the results probably would not have been better if polypropylene mesh or polypropylene mesh based prosthesis was used.

Recurrent hernia still is a major problem. The only randomized controlled trial comparing open suture and mesh repair of small ventral hernias was reported by Luijendijk et al, reporting recurrence rates of 46% and 23% respectively after a follow-up of 36 months and 63% and 32% respectively after a follow-up of 75 months.<sup>1,30</sup> In retrospective studies recurrence rates of 25-63% in suture repair and 8-25% in mesh repair, are reported. Tension free repair of incisional hernia is a prerequisite to prevent recurrence. In CST a tension free repair was accomplished. In literature recurrence rates of 0-28% have been reported for CST, although how follow-up was accomplished is not well documented in most series.<sup>2-12</sup> But it seems impossible to have a reherniation rate, in series about large abdominal wall defects, that is far below the reherniation rate of reconstruction of small abdominal wall defects in a well performed randomized clinical trial.<sup>1,30</sup>

Despite the high recurrence rate in the present study and our retrospective study, CST remains an attractive technique for repair of giant ventral hernias. Most recurrent hernias are small, a symptomatic and need no further treatment, in addition the functional and cosmetic results are good and patients were satisfied.

In a recent other study in 39 patients undergoing CST repair for heavily contaminated abdominal wall defects, similar results were found with respect to complications and reherniation rate (36%).<sup>31</sup> All but one patient indicated satisfaction with the result when compared to their situation before operation. In that study, post-operative Quality of Life was assessed using the SF 36 questionnaire. When compared to the general population patients had an average score or higher on pain, vitality, social functioning, and role limitations (emotional problems), the score was below average on physical functioning, role limitations (physical problems) in general health perception and in mental health.<sup>31</sup>

On the basis of the interim analysis the trial was discontinued, because the frequency of wound complications resulting in subsequent prosthetic loss was unacceptably high. Because underlay repair necessitates transection of the perforating epigastric arteries in patients with prosthetic repair it was expected that this complication could not be prevented, whereas CST remains possible if the epigastric perforators are spared. Impregnation of the e-PTFE patch with silver salts and chlorhexidine might have contributed to this.<sup>23</sup> Recently a prospective randomized controlled trial has started comparing CST with CST + preperitoneal polypropylene mesh support, combining the advantages of CST and prosthetic repair.



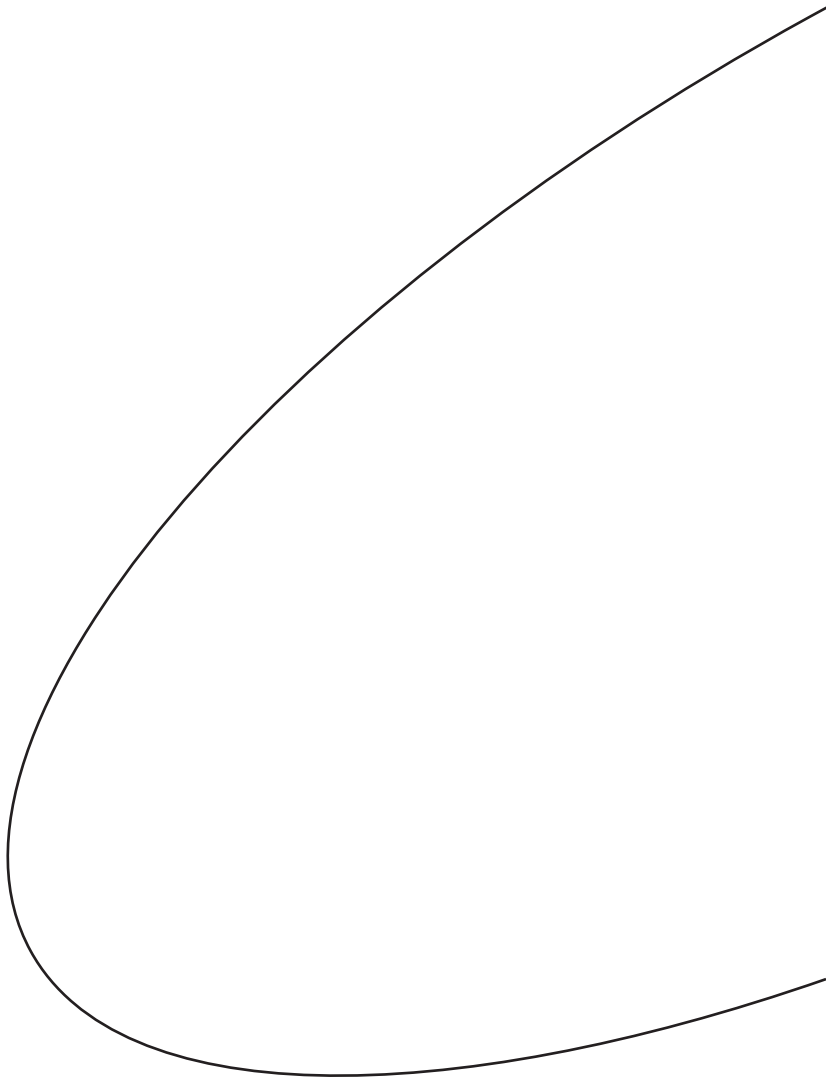
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## endoscopically assisted "components separation technique" for the repair of complicated ventral hernias

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Repair of large incisional hernias and abdominal wall defects by primary closure is often impossible or leads to reherniation rates up to 46%.<sup>1</sup> The use of prosthetic material reduces the risk of reherniation but carries the risk of infection and other complications such as erosion of the skin or viscera.<sup>2-5</sup> In addition, the use of prosthetic material in a contaminated environment is contraindicated, because the risk of infection and the recurrence rate are unacceptably high.<sup>3</sup>

In 1990, Ramirez and colleagues<sup>6</sup> described a new method to repair large abdominal wall defects. Their technique is based on translation of the muscular layers of the abdominal wall to enlarge its surface. Transection of the external oblique muscle, just lateral from the rectal sheath, is the most important part of their technique. A compound flap is created that can be advanced 10 cm at the waistline on both sides, and primary closure without undue tension can almost always be reached. The method is of special interest in the reconstruction of contaminated abdominal wall defects, because it avoids the use of prosthetic material. Until now, the results of the original technique have been reported in 130 patients.<sup>6-10</sup> Reherniation rate ranged from 0 to 14%, although there was no follow-up of at least one year, in most cases. In our own series of 43 patients, we found a reherniation rate of 32% after a median follow-up of 15.6 months.<sup>11</sup>

The original technique has the disadvantage that the skin and subcutaneous tissues must be mobilized over a wide area to reach and expose the aponeurosis of the external oblique muscle, which extends far laterally into the flank. This creates a very large wound, which predisposes to wound complications. Hematoma, seroma, and infection are reported in 11% to 40% of patients<sup>6-10</sup>, and skin necrosis was a frequent complication in the series of Lowe and colleagues.<sup>9</sup> In addition, the original technique is difficult to perform in the presence of an enterostomy. Release of the external aponeurotic fascia through two separate incisions avoids these disadvantages.<sup>11</sup> The present endoscopically assisted technique further reduces the extent of the operation and preserves the blood supply through the intercostal and the epigastric arteries<sup>12</sup>, which may prevent the previously mentioned complications.



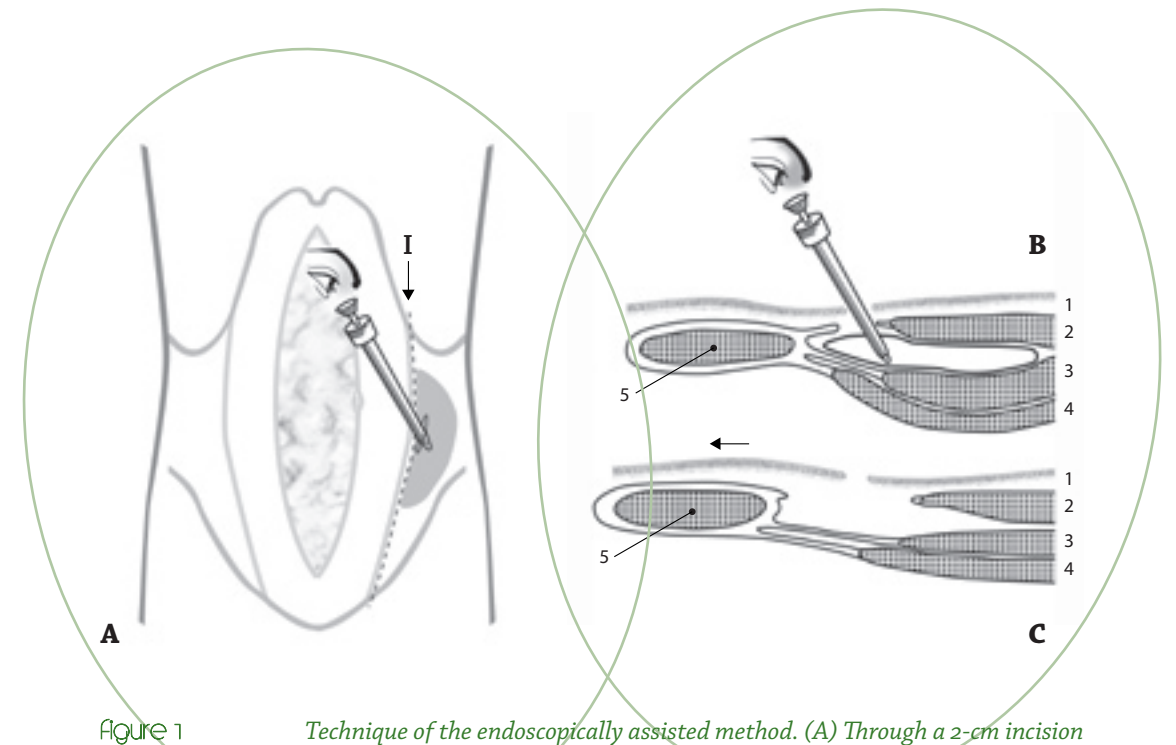
## surgical technique

The abdominal cavity is entered through a median laparotomy. The bowel is freed from the ventral abdominal wall, and the lateral border of the rectal sheath is located by palpation from the inside. A 2 to 4 cm incision in the skin and external oblique aponeurosis is made, just lateral from its insertion into the rectus sheath. The space between the external, and internal oblique muscle is entered, and the aponeurosis of the external oblique muscle is freed from the internal oblique muscle to make space for introduction of the balloon (Figure 1A).

Subsequently, a deflated translucent distention balloon (Preperitoneal Distention Balloon System, Origin Medsystems, Inc, Menlo Park, CA) is introduced into the space between the internal and external oblique muscles (Figure 1B). Under video-endoscopic control, the external oblique muscle is separated from the underlying internal oblique muscle by insufflation of the balloon. After withdrawal of the balloon, the external oblique muscle is lifted with retractors. The aponeurosis of the external oblique muscle is clearly visible after introduction of the 30-degree laparoscope in the intermuscular plane. Then the aponeurosis is transected from symphysis to at least the costal margin with scissors through the skin incision, under video-endoscopic control (Figure 1C). By this means, a well-vascularized compound flap is created that can be advanced to the midline. Existing enterostomies can be left in place, and the creation of new enterostomies is facilitated because shifting of the skin in relation to the rectus muscle does not occur. There are no drains left in place. The skin is closed without tension.

## results

The technique was applied in five patients (Table 1). In two patients (A and B), the defect was closed under clean conditions, and in the other three under contaminated conditions. Patient C had multiple enterocutaneous fistulas in the midline. The continuity of the small bowel was restored, and an ileostomy was created. Patient D had a large incisional hernia in the presence of an ureterostomy in the right lower quadrant and an ileostomy in the left upper quadrant. A pacemaker was present in the left lower quadrant pacing the gracilis muscle, which was used as a new anal sphincter. The ileostomy was dismantled, and an ileo-transversostomy was done after creation of an uretero-cutaneostomy based on the technique of Bricker. Patient E had a midline hernia with a left-sided colostomy after peritonitis caused by anastomotic dehiscence



**Figure 1** Technique of the endoscopically assisted method. (A) Through a 2-cm incision in the skin and aponeurosis of the external oblique muscle, a dilating balloon is introduced via a trocar into the avascular plane between the external and internal oblique muscle. I, the medial border of the external oblique muscle where the aponeurosis is transected. (B) The balloon is insufflated, separating the external (2) from the internal (3) oblique muscle. The skin and subcutaneous (1) remain fixed to the underlying fascia. After removal of the balloon, the myoaponeurotic aponeurosis of the external oblique muscle is lifted with retractors and transected under video-endoscopic control through the skin incision. (C) A compound flap (5) is created that can be advanced over about 10 cm by stretching the internal oblique (3) and transverse abdominis (4) muscle.

one year after Hartmann's procedure for complicated diverticulitis. In patient D and E two extra skin incisions were made to complete transection of the external oblique muscle. No wound or other complications occurred during the post-operative course. All enterostomies functioned well.

## discussion

The endoscopically assisted "components separation technique" is an attractive technique for the repair of large midline incisional hernias without the use of prosthetic material.

Table 1 Patient characteristics and outcome of five patients treated with the endoscopically assisted “components separation technique”.

Patient	Age (y)	Gender	Diagnosis	Size (cm)	Hospital stay (d)	Follow-up (mo)	Hernia
A	60	F	Ventral hernia after laparotomy for sigmoid resection.	23x15	4	10	No
B	41	M	Hartmann’s procedure for perforated diverticulitis, recurrent ventral hernia.	24x17	5	12	Yes
C	26	F	Perforation peritonitis, fascial dehiscence, multiple enterocutaneous fistulas.	28x14	10	24	No
D	59	F	Intra-abdominal sepsis after construction of Indiana pouch for urinary deviation.	17x15	14	8	No
E	72	F	Abdominal sepsis caused by anastomotic leak; Hartmann’s procedure.	21x14	7	2	No

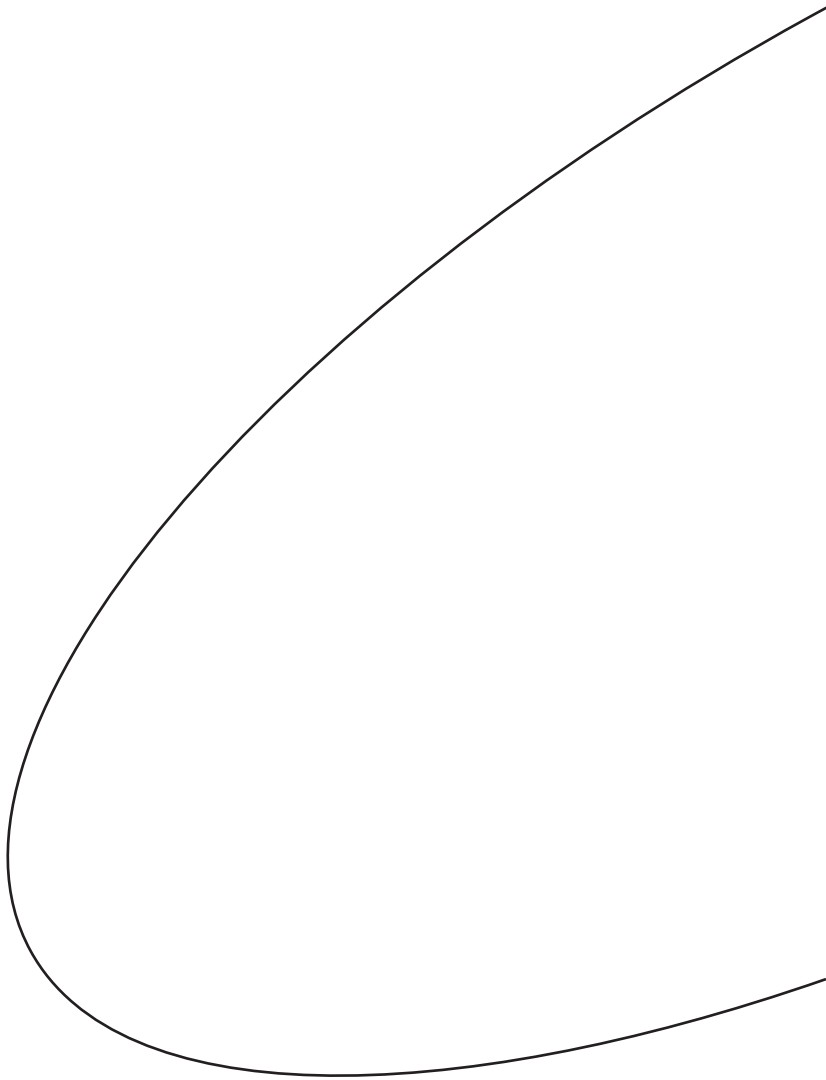
The use of the distention balloon and video-endoscope minimizes tissue trauma and preserves the blood supply of the skin through the epigastric perforators. This is a major benefit in patients in whom the reconstruction is performed in a contaminated environment. In addition, the technique can be used in the presence of an enterostomy, because shifting of the skin in relation to the fascia is prevented. The technique differs from that used by Lowe and colleagues.<sup>9</sup> They used a distension balloon to create a subcutaneous space to transect the external oblique aponeurosis. In our view, their method has no advantage over the classic technique. Balloon dissection in the avascular plane between the internal and external oblique muscle minimizes trauma and creates sufficient space to transect the external oblique muscle and to advance the compound flap.

Creation of a very large wound surface is a major drawback of the classic technique. Wound complications are frequent and vary between 0% and 40% in the published series. In our own series of 43 patients, wound infections were found in 14% and hematoma and seroma formation in 16% of patients.<sup>13</sup> In this series there were no wound complications. Further studies with an adequate number of patients and follow-up are warranted to investigate the potential benefits of the procedure on wound healing and reherniation rate.

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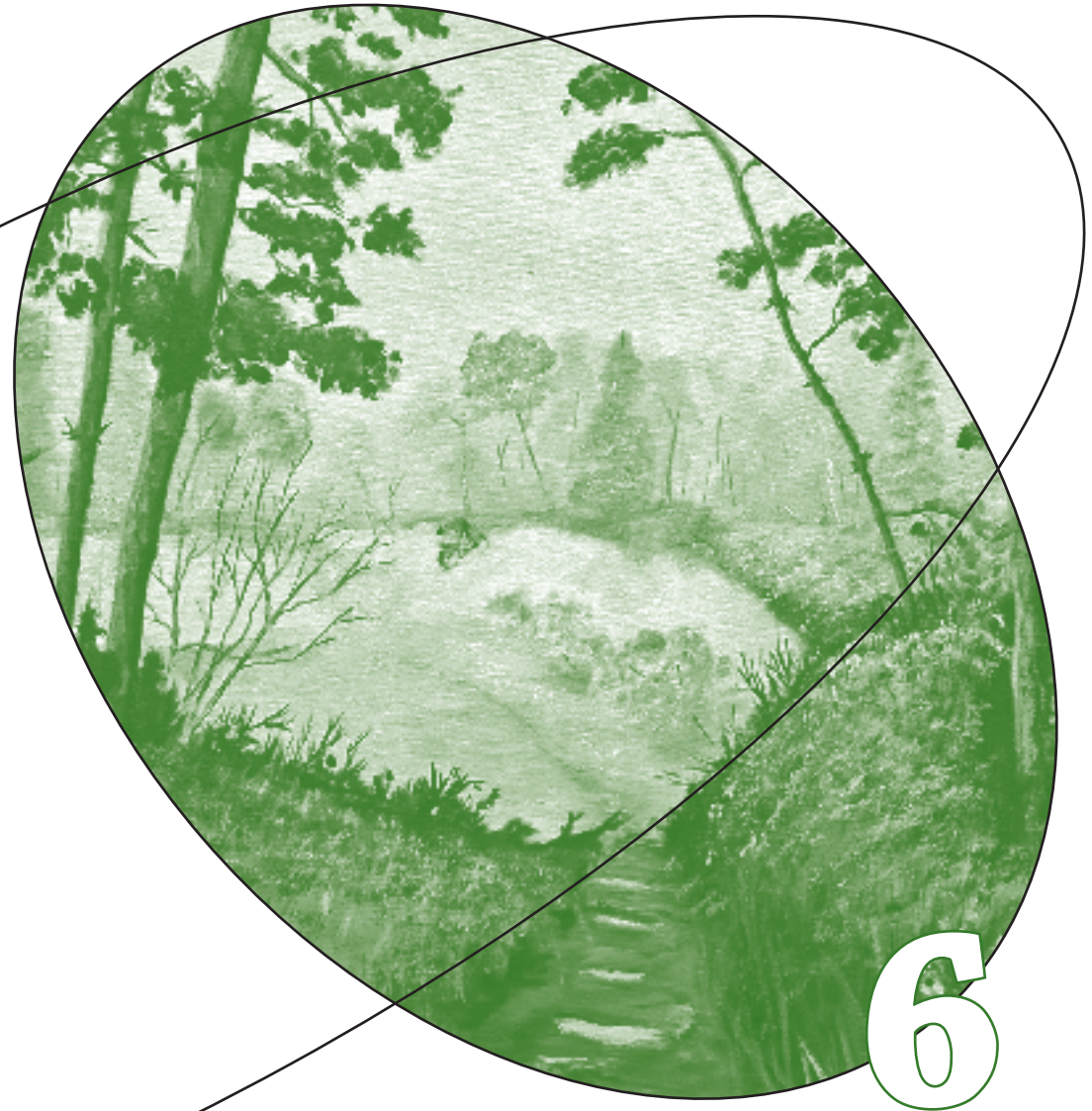
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part 2





6

## repair of large midline incisional hernias with polypropylene mesh: comparison of three operative techniques

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## introduction

Reconstruction of large, midline incisional hernias is still a major problem in general surgery. Reherniation rates of up to 46% have been reported after primary closure.<sup>1,2</sup> Several techniques, either using autogenous material or biomaterials, have been described to repair hernias that cannot be closed primarily. In 1958, Usher introduced the use of a synthetic monofilament polypropylene mesh (PPM) for reconstruction of abdominal wall hernias.<sup>3</sup> Although other prosthetic materials as polytetrafluoroethylene (PTFE), polyester and polyamide meshes and expanded-polytetrafluoroethylene (e-PTFE) patches, have been developed, PPM still is the most widely used mesh. It is a relatively inert material, which is completely incorporated into fibrocollagenous tissue and firmly anchors to the adjacent fascia. However, PPM anchors to all adjacent tissue and, therefore, has the propensity for inducing extensive visceral adhesions, and erosion of the skin or intestines is a well-recognized drawback.<sup>4</sup> Basically, there are three methods for implantation of the mesh: onlay, inlay, and sublay technique. The choice of method is predominantly based on the surgeon's preference.

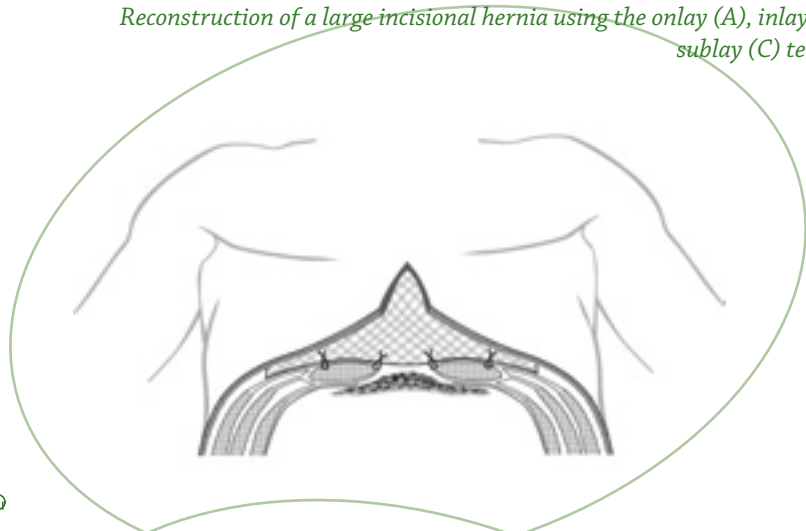
The present study was undertaken to determine the early and late results of the repair of large abdominal wall hernias with PPM to compare for mentioned implantation techniques.

## patients and methods

From January 1987 - September 1999, 53 large abdominal wall hernias were repaired using PPM, in 53 consecutive patients. There were 25 women and 28 men with a mean age of 60.4 (range 28-94). All had midline abdominal wall hernias that could not be closed primarily. All other hernias were excluded from analysis. The patients were operated on in Medical Center Alkmaar using the onlay technique (n = 13, 6 women and 7 men), VU University Medical Center Amsterdam using the inlay technique (n = 23, 9 women and 14 men) and in the Amstelveen General Hospital using the sublay technique (n = 17, 10 women and 7 men), all in The Netherlands.

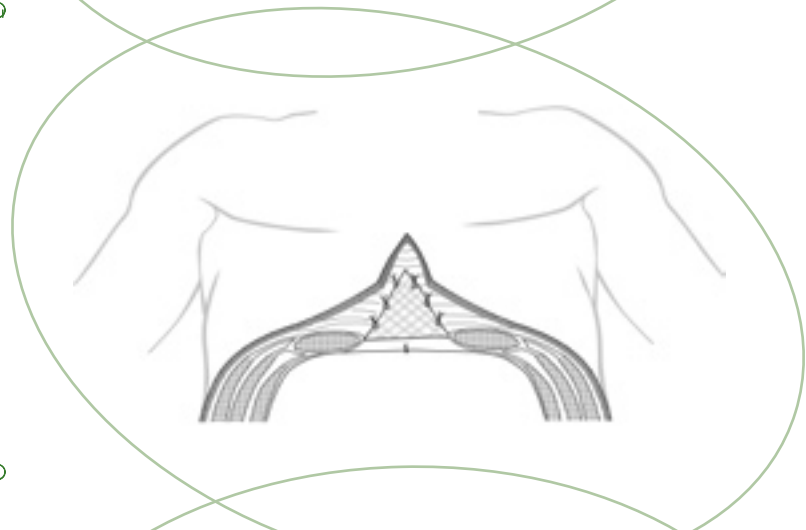
Using the onlay technique, the PPM was positioned on the rectus sheath with an overlap of at least 2 cm and fixed with skin staples. Using the inlay technique, the PPM was fixed to the aponeurotic edge with running non-absorbable suture. Using the sublay technique, the PPM was positioned pre-peritoneal and retromuscular with an overlap of at least 2 cm and fixed with a running polypropylene suture (Figure 1).

Figure 1 *Reconstruction of a large incisional hernia using the onlay (A), inlay (B) and sublay (C) technique.*



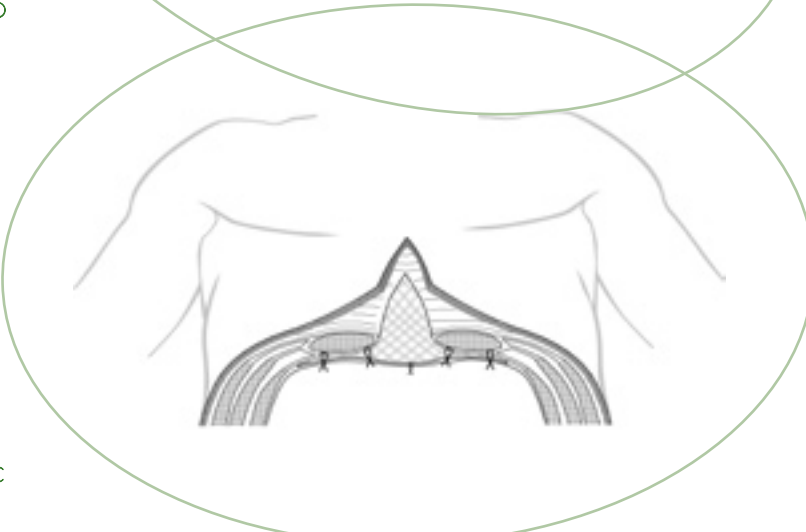
Onlay

Figure 1a



Inlay

Figure 1b



Sublay

Figure 1c

Either the greater omentum or a polyglactin mesh (Vicryl, Ethicon, Johnson & Johnson Medical, Norderstedt, Germany) was interponated between mesh and viscera, in all patients. All patients received thromboembolic and antibiotic prophylaxis.

The records of these patients were reviewed. The following data were extracted from the medical record: size and cause of the hernia, per- and post-operative mortality and morbidity, with special attention to wound complications. All patients were invited to come to the outpatient clinic for physical examination of the abdominal wall at least one year after operation. Patients had a recurrent hernia if a swelling was found and a fascial defect could be palpated during physical examination, if a fascial defect was diagnosed with ultrasonography, or if a patient had an operation for recurrent hernia. Difference in wound complications and recurrent hernia were tested for statistical significance using Chi-squared test per difference on proportions. An alpha of 0.05 was considered statistically significant.

## results

Reconstruction of a large midline incisional hernia with polypropylene mesh was performed in 53 patients. The defect resulted after elective surgery in 39 patients and emergency surgery in 14 patients. Fifteen patients had a recurrent incisional hernia. These recurrences resulted from repair by primary closure in seven patients, by primary closure and onlay PPM support in four patients, and reconstruction with polyglactin mesh ( $n = 3$ ) or a sheep dermal collagen patch ( $n = 1$ ), in four patients. Reconstruction was performed under clean conditions in all patients. There were no differences in demographic parameters and co-morbidity (ASA classification) between the three groups.

### Early complications

The post-operative course was uneventful in 39 patients (74%). Wound complications occurred in 14 patients: Nine in the onlay group, three in the inlay group, and two in the sublay group. Wound complications occurred significantly more in the onlay group (69%, 9 of 13 patients, some patients had more than one complication) than in the inlay group (13%, 3 of 23 patients), and sublay group (12%, 2 of 17 patients) ( $P < 0.05$ ) (Table 1).

Table 1 Early and late post-operative complications in 53 patients with a midline abdominal wall hernia.

Post-operative wound complications	Onlay (n=13)	Inlay (n=23)	Sublay (n=17)	Total
<b>Early complications</b>	17	3	2	22
Haematoma	2	1	1	4
Seroma	9	0	1	10
Infection	3	2	0	5
Skin necrosis	3	0	0	3
<b>Late complications</b>	3	12	2	17
Fistula	0	2	0	2
Reherniation	3	10	2	15

### Late complications

To evaluate the late results, 45 patients, came to the outpatient clinic. The mean follow-up period was 30 months, range 12-108 months. Of the remaining eight patients, two died during the first year after the operation, due to unrelated diseases. Three patients, all without a recurrent hernia, underwent a laparotomy through the mesh within one year after abdominal wall repair. Three patients were lost to follow-up. The mean follow-up of the onlay group was 19.4 months, of the inlay group was 33.2 months, and of the sublay group was 33.9 months. Recurrent hernia was found in 15 patients (33%) after a mean period of 24.5 months (range 8-58 months). Two patients (4%) had an enterocutaneous fistula (Table 1).

The difference in reherniation rate in the inlay group (44%) versus onlay group (23%) and sublay group (12%) approaches conventional level of statistical significance ( $P = 0.07$  ( $\chi^2$ -test, two sided)). Recurrence occurred in seven (47%) of the 15 patients who were treated for recurrent incisional hernia and in eight (27%) of the 30 patients who had their first repair ( $P = 0.18$ ). Recurrent hernia occurred in 13 (33%) of the 39 patients who had an uneventful post-operative course and in two patients (14%) of the 14 in whom the post-operative course was complicated by a seroma ( $n = 1$ ) and a wound infection ( $n = 1$ ).

## discussion

The repair of large abdominal wall hernias that cannot be closed primarily remains a challenge. Polypropylene mesh (PPM) is a frequently used biomaterial to bridge these defects. These reconstructions carry a high complication and reherniation rate. Therefore, we analysed the results of repair of large ventral hernias with PPM in three hospitals in which different methods were used to implant the PPM: the onlay, inlay, and sublay techniques.

In the literature, wound complications, such as hematoma, seroma, and infection are reported in 0-36% of patients after hernia repair, which is similar to the overall results in our series (Table 2 en Table 3).<sup>5-16</sup>

Most wound complications in our series were found in the onlay group (69%), whereas wound complications in the inlay (13%) and sublay group (12%) occurred less frequently.

The high complication rate in the onlay group corroborates with the results in the literature (Table 2). Probably both the extensive dissection to separate the skin and subcutaneous tissue from the fascia and the subcutaneous implantation of a large PPM are responsible for this. The large wound surface predisposes a patient to seroma formation. Moreover, separation of the epigastric perforating arteries may interfere with wound healing and may increase the risk of infection. This is corroborated by the results of a retrospective study in which abdominal wall reconstructions were done with the "components separation technique", a technique in which a similar dissection is done in the subcutaneous plane. In that series, wound complications were found in 40% of patients.<sup>17</sup>

Although the reherniation rate is rather low, varying between 0 and 10% in the literature, the high complication rate discourages further clinical application of the onlay technique.

The inlay technique is an unsuitable technique because the reherniation rate is unacceptably high. This is explained by the small contact area between the mesh and the adjacent aponeurosis, leading to insufficient anchorage of the mesh. Moreover, the sharp edges of the mesh may damage the bowel, resulting in fistula formation, which occurred in two of our 23 patients.

The sublay technique is preferred to bridge fascial defects.<sup>5,10,15,16</sup> In literature, the reherniation- (0-15%) and the wound complication (15-27%) rates are rather low. How-

Table 2 Post-operative complications and reherniation rate in six series of patients in whom the hernia was repaired with PPM onlay technique.

Author	Year	Patients	Complications	Recurrence	Follow-up (Months)	Level of Evidence
Usher et al. <sup>3</sup>	1958	44	?	0	1-14	4
Larson et al. <sup>5</sup>	1978	9	?	0	12-60	4
Lewis et al. <sup>6</sup>	1984	50	Seroma Wound infection	3 2	30	4
Wagman et al. <sup>9</sup>	1985	9		0	14	5
Molloy et al. <sup>8</sup>	1991	50	Haematoma	4	45 (6-120)	4
			Seroma	4		
			Wound infection	4		
			Wound sinus	6		
Liakakos et al. <sup>7</sup>	1994	49	Wound infection	2	0-16	3b

Evidence based medicine: level 1 = randomized clinical trial, level 2 = cohort study, level 3 = case control study, level 4 = case series, level 5 = expert opinion and a = systemic review or b = single study.<sup>18</sup>

Table 3 Post-operative complications and reherniation rate in two series of patients in whom the hernia was repaired with PPM sublay technique.

Author	Year	Patients	Complications	Recurrence	Follow-up (years)	Level of Evidence
Larson et al. <sup>5</sup>	1978	20	?	4	0.5-5	4
Stoppa et al. <sup>10</sup>	1989	368	Haematoma	12	5.5 (0-10)	4
			Woundinfection	44		
Duce et al. <sup>15</sup>	1997	63	Skin necrosis	3	38 (18-66)	4
			Haematoma	2		
			Seroma	6		
			Wound infection	4		
			Wound sinus	2		
Duce et al. <sup>16</sup>	2001	152	Ileus	1	72 (36-124)	4
			Deep vein thrombosis	1		
			Skin necrosis	6		
			Haematoma	7		
			Seroma	14		
			Wound infection	11		
			Pneumonia	2		
			Ileus	3		
			Deep vein thrombosis	1		



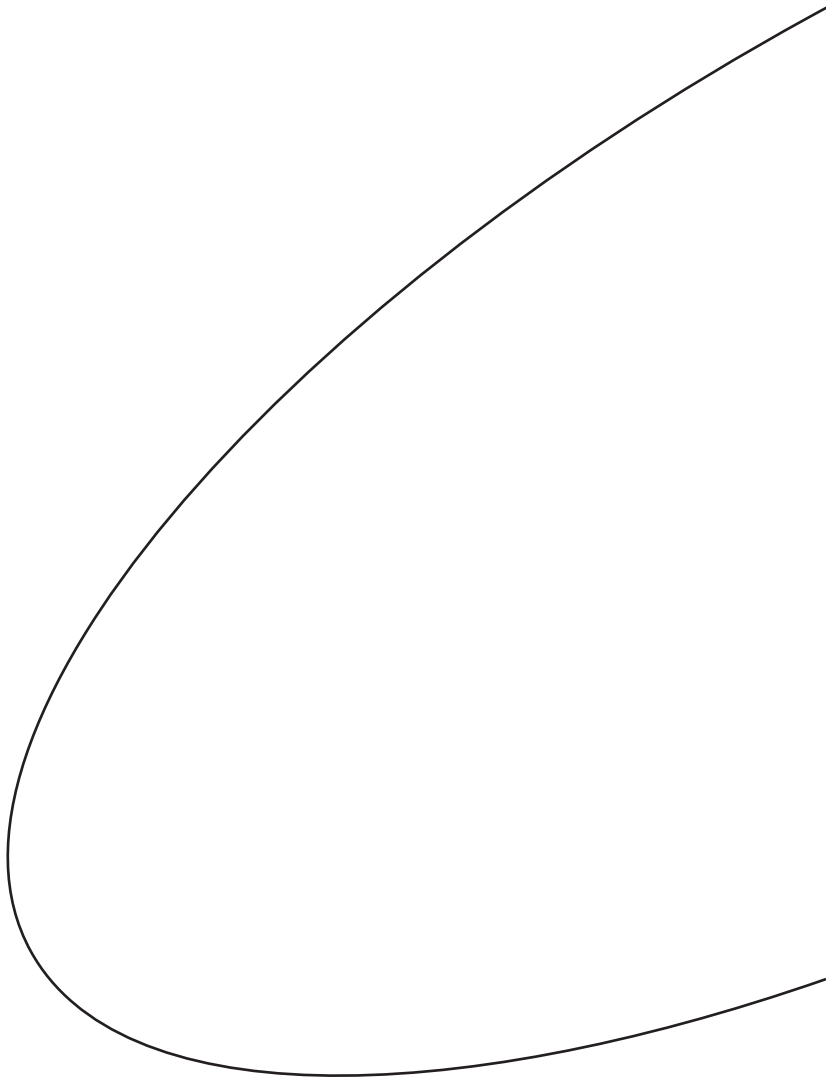
ever, the reherniation rate may be underestimated because follow-up in most series is rather short and most series do not mention how reherniation rate was established. Duce et al., using the Rives technique to repair large incisional hernias, reported a reherniation rate of about 1.5% after a follow-up of 18-124 months; the wound complication rate ranged from 17-27%.<sup>15,16</sup>

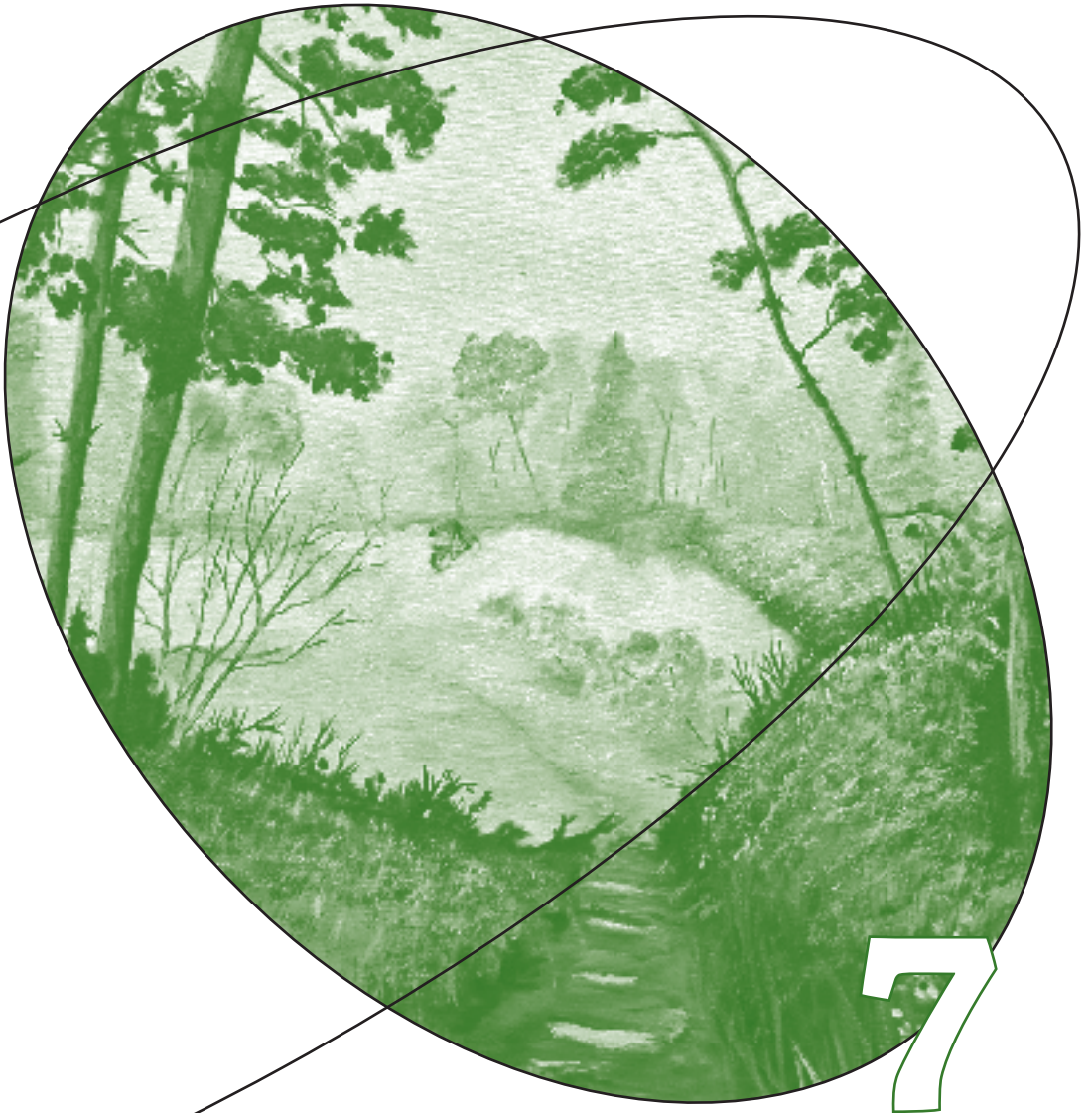
In the prospective randomised trial of Luijendijk et al. comparing suture closure and bridging with PPM with the sublay technique of small incisional hernias, recurrences were found in 43% and 24% of patients, respectively.<sup>2</sup> This supports the idea that the sublay technique seems to be the most proper technique. It provides a large contact area between the PPM and the adjacent aponeurosis, and the mesh is pushed against the ventral abdominal wall, thus creating optimal conditions for good anchorage of the mesh to the fascia. However, true evidence for the application of either technique to repair large ventral hernias is lacking. The studies that were found in Medline had a level of evidence varying between 3b and 5, according to evidence-based medicine.<sup>18</sup>

Our study has several limitations: it is retrospective, observational, and describes a small number of patients. Therefore, our results can only be considered preliminary evidence of the superiority of the sublay technique, as compared to both other techniques. A prospective, randomised clinical trial, comparing different techniques for ventral hernia repair should be initiated.

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# impregnation of e-ptfe abdominal wall patches with silver salts and chlorhexidine diminishes biocompatibility and is associated with an increased herniation rate

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*Submitted*

In surgery, reconstruction of large abdominal wall defects is still a substantial problem. Prosthetic materials are often used to repair these defects.<sup>1</sup> Until now, polypropylene mesh has been the most widely used material for this purpose. However, the propensity to induce adhesions between the mesh and the bowels and erosion of the skin or bowels are major disadvantages.

In the 1980's expanded-polytetrafluoroethylene (e-PTFE) was used to produce patches that had favourable properties with respect to adhesion formation. These patches consisted of PTFE nodules connected by fibrils of the same material. However, the internodal spaces of this highly hydrophobic material were too small (20  $\mu\text{m}$ ) to allow ingrowth of fibrocollagenous tissue, resulting in unacceptably high herniation rates.<sup>2,3</sup> In experimental studies, increased pore size and perforation proved to be effective to improve ingrowth of fibrocollagenous tissue and anchorage of the patch to the adjacent fascia, thus diminishing herniation rates.<sup>4</sup> These principles were applied in a newly designed e-PTFE double layer (e-PTFE DL) patch (Gore-Tex dual mesh with holes, W.L. Gore and associates Inc, Flagstaff, Arizona, USA), which has multiple perforations. A macroporous side of the patch is facing the fascia to promote anchorage and a microporous side is facing to the intra-abdominal viscera to prevent adhesions. To reduce the risk of infection, also an e-PTFE dual patch has been developed, which has been impregnated with two antimicrobial agents, i.e.: silver salts and chlorhexidine di-acetate (Gore-Tex dual mesh plus with holes, W.L. Gore and associates Inc) (e-PTFE DL-plus). The antimicrobials are intended to inhibit bacterial colonization of the patch for up to 10 days after implantation.

Recently, the e-PTFE DL-plus, was used in a prospective randomized trial comparing prosthetic repair (PR) with reconstruction using the "components separation technique" (CST) in patients with very large midline incisional hernias.<sup>5</sup> It was found that clinically relevant seromas occurred significantly more frequent (39%) in patients in whom the abdominal wall was reconstructed with an e-PTFE DL-plus than the patients undergoing CST (20%). Seven of the 18 prosthesis implanted in this study had to be removed as a result of prosthetic infection, which was associated with seroma formation and skin necrosis. This clinical result was in contrast with the design rationale behind the e-PTFE DL-plus patch.

Therefore, the aim of this study was to determine whether impregnation with silver salts and chlorhexidine: (1) influences the biocompatibility of e-PTFE patches and (2) reduces adhesion formation and herniation after repair of abdominal wall defects in rats.

## materials and methods

### Study design

In vitro studies were done to determine the release of silver salts from the patch and to establish the effect of impregnation of e-PTFE with silver salts and chlorhexidine on fibroblast cultures. Subsequently e-PTFE patches with and without silver salts and chlorhexidine were implanted in rats to repair abdominal wall defects in order to determine tissue reaction, herniation rate and adhesion formation.

### In vitro studies

#### Silver ion release

In order to measure the amount of silver-ions released by the e-PTFE DL-plus in vitro, 3 samples of 2 x 2-cm e-PTFE DL-plus were stored in demineralized water (4.0 ml per sample). Ag<sup>+</sup> concentration in the demineralized water was measured after 1, 2, 4, 8, 16 and 32 days using MC6091Ag-9 Combined Silver Electrode (Radiometer, Analytical S.A., France). Similar samples of e-PTFE DL were used as controls.

#### Cytotoxicity of silver salts

In order to study the cytotoxic effects of the silver salts in vitro, 5 e-PTFE DL-plus discs with a diameter of 6 mm were placed in a 6-wells cell culture plate. To each well 5 x 10<sup>5</sup> human dermal fibroblasts were added, suspended in 3 ml of alpha-MEM medium, containing Earle's salts, L-glutamine, 10% fetal calf serum, and gentamicin (50 µg/ml). The wells were subsequently kept in an incubator at 37°C with a humidified atmosphere of air plus 5% CO<sub>2</sub>. Medium was refreshed every 3 days.<sup>6</sup> After 7 days, cell response around the discs was observed by phase-contrast microscopy. Finally, cells were released with 0.25% (w/v) crude trypsin/ 1 mM EDTA (pH 7.2), and cell numbers were assessed using a Coulter Counter. Five e-PTFE DL were used as controls.

### In Vivo study

An abdominal wall defect was created in 30 rats. Rats were randomly assigned into two treatment groups of 15 rats in whom the defect was repaired with either an e-PTFE DL or an e-PTFE DL-plus. The rats were sacrificed after 2 months and autopsy was performed to determine herniation and adhesion rates.

### Animals

Male Wistar rats (Harlan, Zeist, The Netherlands), weighing 180 to 200 g were used. Rats were acclimated to laboratory conditions for 1 week before experimental use and were housed under standard conditions in filter-topped cages (two rats per cage), with free access to animal chow (Hope Farms BV, Woerden, The Netherlands) and water. The study was approved by and carried out in accordance with the guidelines of the Animal Ethics Review Committee of the Faculty of Medicine, Radboud University Nijmegen, The Netherlands.

### Surgical procedure

General anaesthesia was induced by inhalation of a mixture of O<sub>2</sub>, N<sub>2</sub>O and Isoflurane. The ventral side of the rats were shaved and disinfected with iodine tincture. Under clean conditions, a midline laparotomy was performed and a 2 x 3 cm full thickness abdominal wall defect was created. The defect was subsequently reconstructed with an underlay of 2.5 x 3.5 cm e-PTFE DL or an underlay of 2.5 x 3.5 cm e-PTFE DL-plus (fifteen rats per group). Prostheses were sutured to the fascia with an overlap of at least 2 mm with 8 interrupted, non-resorbable 4/0 Polypropylene sutures (Prolene Ethicon, Johnson & Johnson Medical, Norderstedt, Germany). The skin was closed using iron wound clips. Post-operatively the wound was daily inspected during the first 14 days, on day 30, and on day 60.

### Autopsy

Rats were sacrificed two months after surgery by O<sub>2</sub>/CO<sub>2</sub>-asphyxiation by the animal laboratory-assistent. At autopsy the abdomen was opened via the lateral side. Herniation and adhesions was scored by two observers (TdVR and AWM). The observers were blinded to the group the rats had been assigned to. The presence of herniation was scored by inspection of mesh-fascia interface for defects. Adhesions of the omentum and viscera to the mesh were scored according to Jenkins.<sup>7</sup> In short: 0 = no adhesion, 1 = minimal adhesion that could be freed by gentle blunt dissection, 2 = moderate adhesion that could be freed by aggressive blunt dissection, 3 = dense adhesion that require sharp dissection.

The mesh together with approximately 1 cm of surrounding fascia was dissected, fixed in 4% buffered neutral formalin and processed in a Leica Histokinetic for paraffin em-



bedding. The processing technique involved dehydration of the material with graded ethanol solution, clearing in Histoclear and infiltrating with paraffin. The paraffin embedded blocks were sectioned at 5 microns on a rotary microtome, deparafinized and stained with hematoxylin and eosin. Capsule quantity, capsule quality, interface and ingrowth of cells into the patch were assessed (three sections per tissue sample).<sup>8</sup> For each section we used a semi-quantitative score with a range from 1-4 (Table 1).

Table 1 Semi quantitative score of light microscopic view of patch and surrounding tissue.

	Score = 1	Score = 2	Score = 3	Score = 4
Capsule quantity	>30 cells	10-30 cells	9-5 cells	<5 cells
Capsule quality	Mature fibroblasts	Immature fibroblasts	Granulous, dense fibroblasts and inflammatory cells	inflammatory cells
Interface	>5 cells	2-5 cells	1 cell	no cells
Ingrowth	no cells	1 cell	2-5 cells	>5 cells

## results

### In vitro studies

After storage of the e-PTFE DL-plus in demineralized water, the mean  $\text{Ag}^+$  concentration was 3.9 mmol/l after one day, which increased to 6.9 mmol/l after 32 days of storage (Figure 1). Logically, the e-PTFE DL did not release any silver ions.

Using phase-contrast microscopy, the fibroblast cultures showed a zone around all e-PTFE-DL-plus where cell growth clearly was inhibited. This zone was not present around the control patches. The mean number of fibroblasts ( $\pm$  S.D.) in the cell culture

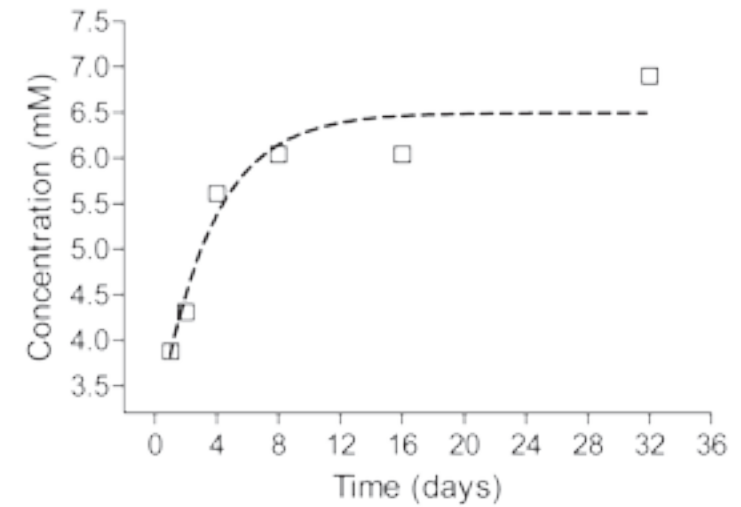


Figure 1  $\text{Ag}^+$  release from the e-PTFE double layer patch with silver salts and chlorhexidine in demineralized water.

containing the e-PTFE DL-plus was  $2.1(\pm 1.9) \times 10^4$  per ml, which was significantly lower compared with the e-PTFE DL,  $10.2 (\pm 2.2) \times 10^4$  cells per ml ( $P < 0.0001$ , unpaired t-test, Welch corrected).

### In vivo study

One rat in each group died within the first week post-operatively due to massive herniation and strangulation of the bowel. None of the other rats developed wound complications or wound infection. During the autopsy the (colour) difference between e-PTFE DL patch and e-PTFE DL-plus patch could not be recognized anymore.

Herniation was found in 8 of the 15 rats (53%) in the e-PTFE DL and 12 of the 15 rats (80%) of the e-PTFE DL-plus. Statistical testing showed this difference approaches conventional level of statistical significance ( $P = 0.06$ ,  $\chi^2$ -test, one sided) (Table 2).

The median (range) adhesion score in the rats with an e-PTFE DL-plus was 2 (1-3) and did not differ significantly from the score in the e-PTFE DL, which was 1 (0-2) ( $P = 0.972$ , Fisher exact test) (Table 2).

table 2 Results of herniation rate and adhesion score.

	e-PTFE DL (n = 15)	e-PTFE DL-plus (n = 15)	Significance
Herniation	8 (53%)	12 (80%)	$P = 0.06$
Adhesion score	1 (0-2)	2 (1-3)	$P = 0.972$

Histopathological examination of the patch-fascia specimens in the e-PTFE DL showed a thin capsule of mature fibrocollagenous tissue that surrounded the entire patch, which was separated from the patch by a layer of inflammatory cells such as: monocytes and phagocytes. No cells were seen in the patch on both the macroporous and microporous side (Figure 2 + Table 3). Further, no blood vessels were seen in the capsule, blood vessels were only observed in the surrounding fat tissue.

The e-PTFE DL-plus showed a similar pattern of a thin capsule of mature fibrocollagenous tissue that surrounded the entire patch, which was separated from the patch by a layer of inflammatory cells such as: monocytes and phagocytes. However the surrounding fat tissue showed fat necrosis and the fibrocollagenous tissue and muscles were infiltrated massively with granulocytes (Figure 3).

table 3 Results of semi quantitative score of light microscopic view of patch and surrounding tissue. (NS = not significant)

	e-PTFE DL mean (range)	e-PTFE DL-plus mean (range)	
Capsule quantity	4 (3-4)	4 (3-4)	NS
Capsule quality	3 (2-4)	4 (2-4)	NS
Interface	3 (0-4)	3 (0-4)	NS
Ingrowth	1	1	NS

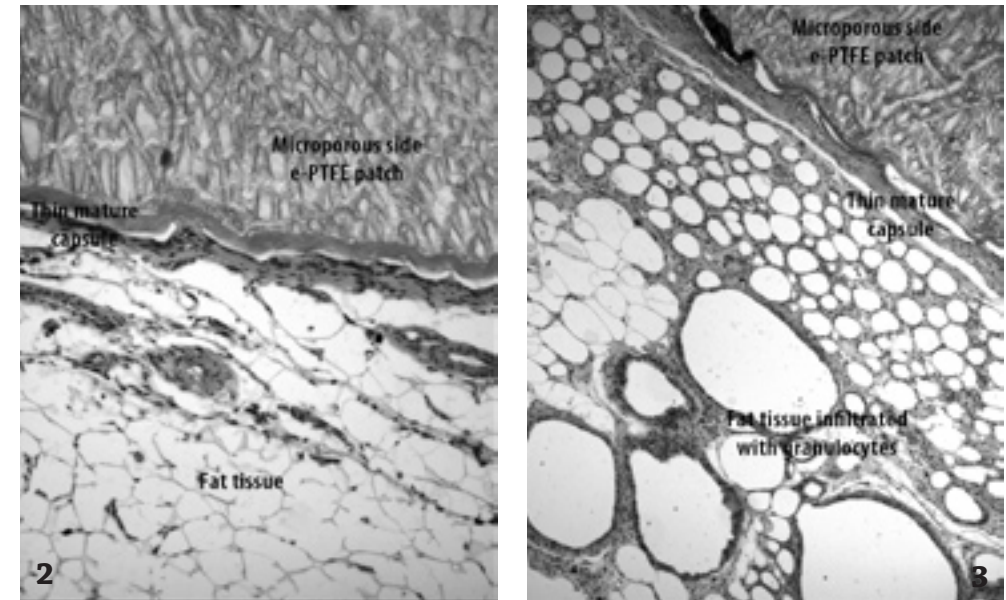


Figure 2 Light microscopic view of an e-PTFE double layer patch and surrounding tissue after HE staining, shows a thin capsule of mature fibrocollagenous tissue that surrounded the entire patch, separated by a layer of monocytes and phagocytes. No cells or ingrowth was seen in the patch.

Figure 3 Light microscopic view of an e-PTFE double layer patch with silver salts and chlorhexidine and surrounding tissue after HE staining, shows necrosis in fat tissue surrounding the patch and the fibrocollagenous tissue is infiltrated with granulocytes. No cells or ingrowth was seen in the patch.

## discussion

Biocompatibility has been defined as the ability of a material to perform with an appropriate host response in a specific application. This is a complex definition and constitutes of a wide variety of different material properties, like mechanical, bulk- and surface physicochemical as well as cytotoxic characteristics. In view of this, the current study proved that the impregnation of the e-PTFE DL patch with silver salts and chlorhexidine lowers the biocompatibility of the patch, due to the cytotoxic release of silver salts and chlorhexidine. The resulting inflammatory response around the patch was associated with an increased herniation rate, when used to repair abdominal wall defects in rats. On the other hand, the non-impregnated e-PTFE DL proved to be non

toxic, in-vitro as well as in-vivo and was well tolerated by the host tissue. Evidently, the addition of silver salts and chlorhexidine does not result in an improvement of the anchorage of the e-PTFE double layer patch to the fascia and in a reduction of adhesion formation on the microporous side. Although the number of rats used in this study only shows a strong trend and reaches significant level of evidence ( $P = 0.06$ ). Besides, we noticed that both patches showed no ingrowth of fibrocollagenous tissue into either side of the patch, which can be explained by the small internodal spaces (20  $\mu\text{m}$ ). This lack of ingrowth, resulted in a high herniation rate which is in corroboration with former experimental and clinical studies using the e-PTFE soft tissue patch in the same rat model.<sup>2-4</sup> Experimental studies with the same rat model using polypropylene (based) mesh and the same operation technique shows an incredible lower herniation rate.<sup>9-11</sup>

Infection of e-PTFE patches invariably results in loss of the prosthesis. In order to diminish the risk of infection silver salts ( $\text{AgNO}_3$ ) and chlorhexidine were added to the patch.<sup>12</sup> The therapeutic value of silver has been recognized for many years. Soluble silver salts are used primarily as topical antimicrobial agents, to provide protection against infection in burn patients and to prevent ophthalmia neonatorum. In vivo, silver salts are reduced to ionic silver. The antimicrobial action of silver is mainly due to the formation of complexes with the micro-organism's cellular proteins, causing denaturation and precipitation of those proteins. Chlorhexidine is a powerful antimicrobial that is widely used as a preservative in ophthalmic solution and other pharmaceutical agents. Its antibacterial action results from binding with and subsequent disruption of the semi-permeable membrane of the cell wall of micro-organisms. Moreover, both antimicrobial work synergistically as has been demonstrated in studies in which the action of each agent alone and both agents together have been assessed in active cultures of test organisms.<sup>12,13</sup>

Impregnation of e-PTFE with silver salts and chlorhexidine lowered the biocompatibility of the patch as demonstrated in this study. In-vitro, the release of silver salts from the e-PTFE DL-plus in demineralized water resulted in toxic concentrations within 24 hours. In fibroblast cultures, release of silver salts and/or chlorhexidine resulted in cell death around the patch. In vivo (rat-experiment), the toxicity of the e-PTFE DL-plus patch was even more outspoken and characterized by the fat tissue necrosis and the massive infiltration of granulocytes. This aggravated inflammatory response may be an explanation for the massive seromas that were found in 38% of the patients in a recently performed prospective study.<sup>5</sup> Rats are very resistant to infection so it did not surprise us that none of the rats in this experiment actually developed a wound infection.

Hidalgo et al. studied the cytotoxic mechanisms of silver nitrate in human dermal fibroblasts. They found that after incubation of human dermal fibroblast with silver, DNA synthesis was inhibited at concentrations of 82.4  $\mu\text{M}$  after 24 hours. This resulted in a significant loss of cell protein as well as inhibition of proliferative capacity. Prolonged  $\text{AgNO}_3$  exposure resulted even in  $\text{Ag}^+$ -dependent cell death.<sup>14</sup> The  $\text{Ag}^+$  concentration found in this study is much higher compared to the toxic level reported by Hidalgo et al. The toxic effects of  $\text{AgNO}_3$  explain the increased inflammatory response and fat necrosis around the e-PTFE DL-plus that were implanted in the rats. Chlorhexidine, which is cytotoxic even at low concentrations, may have contributed to diminishing the biocompatibility of the patch although it is known that serum may protect against its toxic effects.<sup>15</sup>

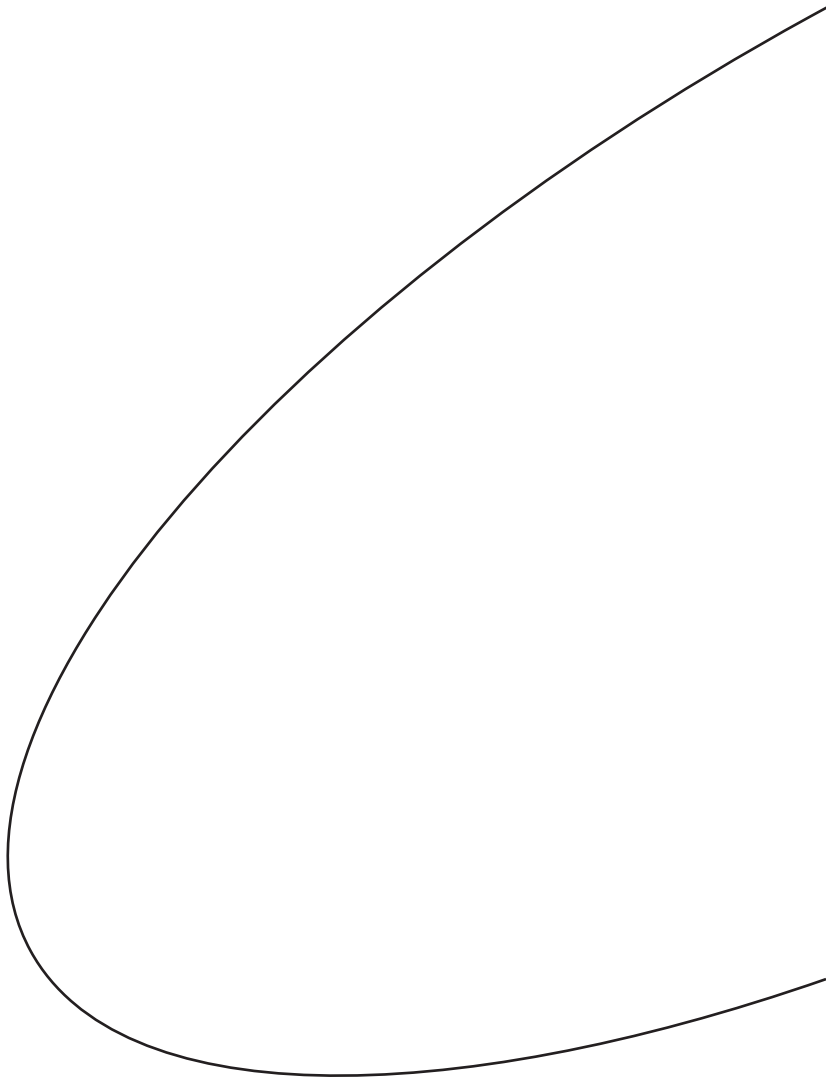
Since prosthetic infection was associated with seroma formation in our clinical study, impregnation of e-PTFE patches may even have increased the risk of infection.<sup>5</sup> The lack of tissue adhesion due to the hydrophobicity of the e-PTFE patches and the small pore size which prevents the removal of necrotic material and bacteria, make these patches at risk for infection. Early ingrowth of fibrocollagenous tissue into e-PTFE patches is the best way to diminish the risk of infection. The formation of seroma hampers this process. It is thought that the high  $\text{Ag}^+$ -ion concentration around the patch prevents colonization and infection. However,  $\text{Ag}^+$ -ions will be inactivated by  $\text{Cl}^-$ -ions that are present in the exudate around the patch by forming  $\text{AgCl}_2$ . Therefore, impregnation with silver salts and chlorhexidine may increase the risk of infection by diminishing biocompatibility, thus increasing the inflammatory response. Probably,  $\text{Ag}^+$ -ions and chlorhexidine will not prevent colonization of the patch but only delay the occurrence of a clinical manifest infection, which may explain the late infections in our previous clinical study.<sup>5</sup>

The cytotoxic effects of silver salts and chlorhexidine may also have contributed to the increased herniation rate, as well. First: due to disturbed wound healing. This may result in seroma formation, interference with adhesion of fascia to the patch or delay in the formation of the fibrocollagenous envelope around the patch. Second: because necrosis and an increased inflammatory response are associated with increased collagen breakdown which may cause tearing of sutures through the fascia. One could expect that the increased inflammatory response around the patch was associated with increased adhesion formation, which was not found in the present study, although the adhesion score in the e-PTFE DL-plus rats tended to be higher than in the control group.

In conclusion: impregnation with silver salts makes the e-PTFE DL-plus patch less biocompatible, due to cytotoxic effect and is accompanied by trend to a higher herniation rate.

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# interposition of polyglactin mesh does not prevent adhesion formation between viscera and polypropylene mesh

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## introduction

Reconstruction of large abdominal wall defects is a challenging problem. The lack of sufficient fascia requires the insertion of prosthetic material. Polypropylene mesh (PPM) is still the most widely used material for this purpose. It is a relatively inert material that is completely incorporated into the fibrocollagenous tissue and firmly anchors to the adjacent fascia. It is cheap and usually suffices well, if covered with full-thickness skin. The propensity to induce visceral adhesions is a well-recognized drawback.<sup>1-3</sup> Visceral adhesions may cause serious complications including small bowel obstruction, inadvertent enterotomy on re-entry of the abdomen, and chronic abdominal pain.<sup>4</sup> Most devastating, however, is erosion of the PPM into the bowel at adhesive sites because of shrinkage and subsequent enterocutaneous fistula formation.<sup>1,5</sup>

After intra-abdominal catastrophes or colorectal surgery, the greater omentum or peritoneum are not available to separate the bowel from the prosthetic material in a substantial number of cases. Under these circumstances, an interface between the intra-abdominal viscera and the prosthesis is desirable to prevent contact between the bowel and the PPM. Many surgeons interpose a resorbable polyglactin 910 mesh (PGM) between the PPM and the viscera, with the assumption that viscera do not adhere to PGM. No clinical or experimental data are available to support this approach.

The aim of this study was to determine whether interposition of a resorbable mesh between the PPM and the intra-abdominal viscera influences biocompatibility, adhesion formation, and herniation.

## materials and methods

An abdominal wall defect was created in 80 rats. Rats were randomly assigned to two treatment groups of 40 rats each for repair of the defect with either PPM (Prolene mesh, Ethicon, Johnson & Johnson Medical, Norderstedt, Germany) or PPM-PGM (Prolene mesh and Vicryl mesh, Ethicon, Johnson & Johnson Medical). The rats were sacrificed after 1, 2, 3, and 6 months (n = 10) to determine herniation and adhesion rates and to biopsy mesh-fascia interface.

### Animals

Male Wistar rats (Harlan, Zeist, The Netherlands), weighing 180 to 200 g were used. Rats were acclimated to laboratory conditions for 1 week before experimental use and were housed under standard conditions in filter-topped cages (two rats per cage), with free access to animal chow (Hope Farms BV, Woerden, The Netherlands) and water. The study was approved by and carried out in accordance with the guidelines of the Animal Ethics Review Committee of the Faculty of Medicine, Radboud University Nijmegen, The Netherlands.

### Surgical procedure

General anaesthesia was induced by inhalation of a mixture of  $O_2/N_2O$  and isoflurane. The abdomen was shaved and disinfected with iodine tincture. Under clean conditions, a midline laparotomy was performed, and a 2- x 3-cm full-thickness abdominal wall defect was created. The defect was subsequently reconstructed with 2.5- x 3.5-cm polypropylene mesh (Prolene mesh, Ethicon, Johnson & Johnson Medical) or 2.5- x 3.5-cm polypropylene mesh with PGM (Prolene mesh and Vicryl mesh, Ethicon, Johnson & Johnson Medical) in underlay position, with the PGM facing the viscera. Prostheses were sutured to the fascia with an overlap of at least 2 mm with 8 interrupted, non-resorbable 4/0 polypropylene sutures (Prolene, Ethicon, Johnson & Johnson Medical).<sup>6-11</sup> The skin was closed using iron wound clips. The wound was inspected daily during the first 14 days and monthly thereafter.

### Autopsy

Rats were sacrificed 1, 2, 3, and 6 months ( $n = 10$ ) after surgery by  $O_2/CO_2$ -asphyxiation. At autopsy the abdomen was opened by lateral incision. The presence of herniation and adhesions was scored by two observers (TVR and MK). The observers were blinded to the group the rats had been assigned to. Adhesions of the omentum and viscera to the mesh were scored according to Jenkins.<sup>12</sup> In short: 0 = no adhesion, 1 = minimal adhesion that could be freed by gentle blunt dissection, 2 = moderate adhesion that could be freed by aggressive blunt dissection, 3 = dense adhesion that requires sharp dissection.

The mesh together with approximately 1 cm of surrounding fascia was dissected, fixed in 4% buffered neutral formalin, and processed in a Leica Histokinect for paraffin embedding. The processing technique involved dehydration the material with graded ethanol solution, clearing in Histoclear, and infiltrating with paraffin. The paraffin-

embedded blocks were sectioned at 5 microns on a rotary microtome, deparafinized, and stained with hematoxylin and eosin. During histological examination, capsule quantity, capsule quality, and interface mesh were analysed.<sup>13</sup>

### Statistical analysis

Statistical analysis was performed by means of the GraphPad Prism 4.00 software (GraphPad Software, San Diego, CA). Herniation rates were compared using the Fisher's exact test, and adhesion scores were compared using the Mann-Whitney test. All tests were two-sided; the level of statistical significance was set at  $P < 0.05$ .

## results

In the PPM group, one rat died within the first post-operative week because of unknown reasons. Five rats had a hematoma after PPM reconstruction, found during autopsy (1 and 2 months after implantation). No wound infection or enterocutaneous fistula occurred. None of the rats had a hernia at sacrifice after 1, 2, and 3 months. At 6 months, one of the 10 rats had a herniation (Table 1).

table 1 Herniation rate for PPM versus PPM-PGM for each time point.

Months	PPM			PPM-PGM			<i>P</i> (Fisher exact)
	Rats (n)	No Hernia (n)	Hernia (n)	Rats (n)	No Hernia (n)	Hernia (n)	
1	10	10	0	10	8	2	0.47
2	10	10	0	10	10	0	1.0
3	10	10	0	9	9	0	1.0
6	9	8	1	10	7	3	0.58
<b>Total</b>	<b>39</b>	<b>38</b>	<b>1</b>	<b>39</b>	<b>34</b>	<b>5</b>	<b>0.11</b>

In the PPM-PGM group, two rats died within the first post-operative week, one because of strangulation of the bowel in a herniation and the other because of unknown reasons. Three rats had a hematoma after PPM-PGM reconstruction that was found during autopsy (2 months after implantation). No wound infection or enterocutaneous fistula occurred. Surprisingly, five herniations occurred in two rats at 1 month (one of which died) and in three rats at 6 months. The total incidence of herniation did not differ between the groups (PPM, 1 of 39 *versus* PPM-PGM, 5 of 39;  $P = 0.1080$ ). Furthermore, there were no statistically significant differences in herniation rate at the time points evaluated, up to 6 months post-surgery (Table 1).

The adhesion score in the PPM group (median, 3; range 2-3) did not differ from the score in the PPM-PGM group (median, 3; range 2-3) at 1, 2, 3, and 6 months (Table 2).

### Histology

Light microscopy in the PPM group showed a thin immature capsule of a few layers of macrophages around the polypropylene fibres, with neo-vascularisation in the interstitium between the fibres, after 1 month of implantation. More macrophages and stroma were seen in the fibrocollagenous tissue surrounding the polypropylene fibres after 2 months. The capsule around the polypropylene matured and the monocytes between the polypropylene fibres gradually disappeared in the following months. In all rats, the greater omentum covered the inner side of the PPM.

Similar histology was found after implantation of PPM-PGM. However, the inflammatory response was more evident in the first month after implantation. The immature capsule around the polypropylene fibres was infiltrated by macrophages and granulocytes. The PGM dissolved within 2 months after implantation.

### discussion

The aim of this experimental study was to investigate whether interposition of a resorbable mesh between the PPM and abdominal viscera influences the biocompatibility of the PPM, the formation of adhesion, or herniation. It was demonstrated that the interposition of a PGM elicited a more evident early inflammatory response and did not alter adhesion formation between the viscera and the PPM, nor influence herniation.

table 2 Adhesions of the omentum and viscera to the mesh. 0= no adhesion, 1= minimal adhesion that could be freed by gentle blunt dissection, 2= moderate adhesion that could be freed by aggressive blunt dissection, 3= dense adhesion that requires sharp dissection.

Months	Grade	PPM rats (n)	PPM-PGM rats (n)	P
1	grade 1			0.74
	grade 2	1		
	grade 3	9	10	
2	grade 1			0.48
	grade 2	3	5	
	grade 3	7	5	
3	grade 1			0.55
	grade 2	5	3	
	grade 3	5	6	
6	grade 1			0.73
	grade 2	5	4	
	grade 3	4	5	

Abdominal viscera adhere to prosthetic material after implantation to reconstruct an abdominal wall defect, a process known as bio-adhesion. The prosthetic material elicits an inflammatory response that is accompanied by exudation of fibrinogen and activation of the coagulation cascade, resulting in the formation of fibrinous adhesions between prosthesis and viscera.<sup>14,15</sup> Fibrinous adhesions may be degraded by the fibrinolytic system; however, the ongoing foreign body reaction around the prosthesis disturbs fibrin degradation. As a consequence, fibrinous adhesions persist and are turned into fibrous adhesions after infiltration with fibroblasts and collagen deposition. The adhesions are continuous with the newly formed fibro-collagen that surrounds the prosthetic material. Visceral adhesions can be harmful for several reasons, including bowel obstruction, enterocutaneous fistula formation, and bowel perforation at subsequent surgery.<sup>4</sup> Adhesive small bowel obstruction has been described after mesh insertion in patients, but incidences are sparingly documented and no differentiation has been made by type of mesh.<sup>16</sup> Perforation of adhered bowel through the mesh ending into an enterocutaneous fistula is typically seen after surgical wound infection. When the wound heals by secondary wound healing and scar tissue forma-



tion with contraction, the PPM wrinkles, compromising the bowel wall adhered to the mesh and the surrounding tissue.<sup>1</sup> At surgical lysis of adhered bowel on re-entry of the abdomen via the mesh, an inadvertent enterotomy may occur, resulting in significant morbidity and mortality.<sup>17</sup> None of these adhesion-related complications have been documented in animals. PPM-PGM, however, is not expected to reduce these complications in clinical practice, based on the similar adhesion formation rate and the even more pronounced inflammatory response in comparison with PPM. Thus, the advice to interpose PGM between PPM and the viscera in the absence of peritoneum or greater omentum to prevent adhesion formation is questionable, as is the assumption that PGM facilitates the removal of PPM if wound sepsis occurs.<sup>18</sup>

The period of increased inflammatory response coincides with the breakdown and removal of PGM in 6 to 8 weeks, mediated by inflammatory cells. The first weeks after surgical trauma are particularly crucial for adhesion prevention, and diminishing inflammation rather than increasing inflammation in the peritoneal cavity should be the goal. A biomaterial commencing to breakdown after complete adhesion-free healing of damaged peritoneal surfaces would therefore be more ideal as an interface between bowel and PPM than PGM.

The authors, like others, choose not to remove the omentum or epididymal fat pads in this hernia model.<sup>6,8-11</sup> In the present study, omentum or epididymal fat pads were not removed to avoid additional surgical trauma. This might be considered as a weakness of the study, although the bowel may strongly adhere to the PPM even in the presence of omental tissue.<sup>6</sup>

PGM is incorporated in PPM as a commercially available light weight mesh (Vypro mesh, Ethicon, Johnson & Johnson Medical) with the benefits of less biomaterial implanted after absorption of the polyglactin, less shrinkage, and better handling for the surgeon.<sup>19</sup> In contrast to the PPM-PGM, polyglactin fibres are completely mixed with the polypropylene fibres and do not serve as an interface. In animal models, however, Vypro mesh was found to elicit an increased inflammatory response after implantation in rats as compared with PPM, although PPM seems to result in less fibrosis.<sup>20-22</sup> Adding PGM to a Vypro mesh also resulted in increased adhesion formation compared with Vypro mesh alone, as demonstrated in a laparoscopic rabbit model.<sup>23</sup>

PGM to separate viscera from PPM is not suitable for preventing adhesions, and further research is not warranted, based on the present results and those of others. The question remains what type of layer is more suitable and effective to separate viscera and mesh in the first weeks after implantation and does not impair ingrowth into the fascia. In two recent experimental studies, PPM coated with sodium hyaluronate/car-

boxymethylcellulose (Sepramesh, Genzyme Corporation, Cambridge, USA) showed promise significantly reducing adhesion formation without jeopardizing anchorage characteristics.<sup>10,11</sup> Another coated PPM (Proceed, Ethicon, Johnson & Johnson Medical) is commercially available. It is a three-layer mesh: The outer layer is of polypropylene (fascial side), the inner layer is absorbable oxidized regenerated cellulose (abdominal side), and these two layers are separated by a layer of polydioxanone.

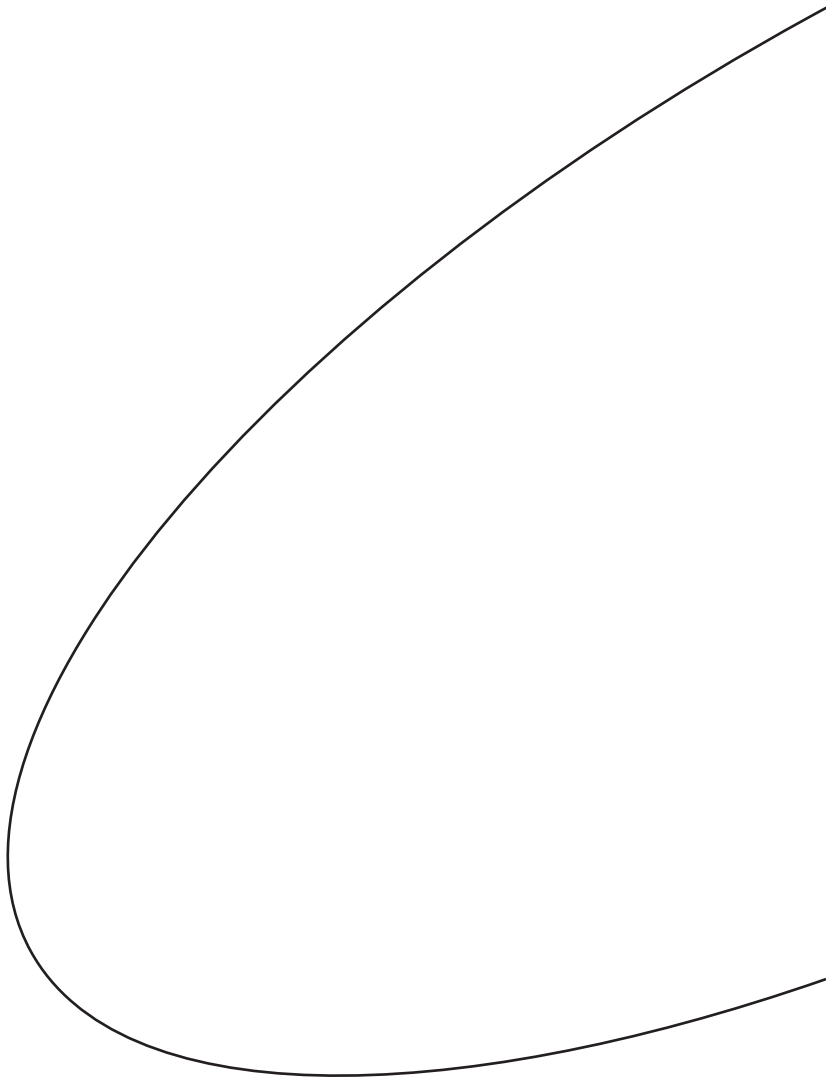
Although this concept seems promising, no experimental or clinical data are available.

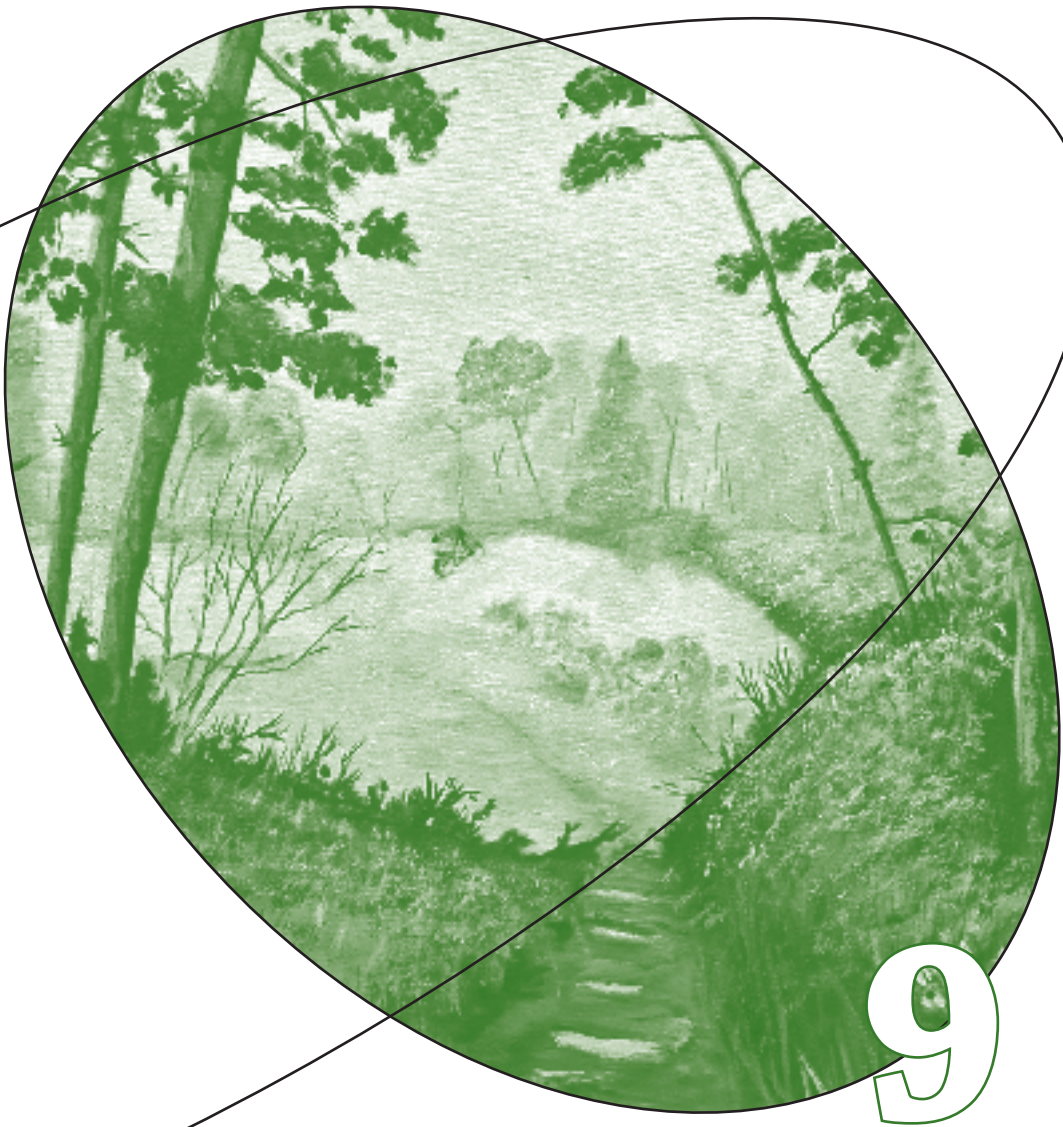
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9

## adhesion formation and herniation differ between meshes used for abdominal wall reconstruction

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## introduction

Incisional hernias occur in approximately 10-20% of patients after abdominal surgery causing signs varying from mild discomfort and pain to incarceration and strangulation of bowel loops.<sup>1,2</sup> Prerequisite for successful treatment of incisional hernias is tension-free repair, which often demands the use of prosthetic meshes to bridge the abdominal wall defect. Polypropylene is the most commonly used biomaterial in incisional hernia repair. This macroporous mesh shows good anchorage to the fascia by ingrowth of fibroblasts.<sup>3</sup> Great drawback is the propensity of adhesion formation at the peritoneal side of the mesh introducing risk of bowel obstruction and fistula formation.<sup>3-5</sup> Microporous meshes, like expanded-polytetrafluoroethylene, were developed to withstand formation of adhesions and associated complications. However, ingrowth of fibrocollagenous tissue appeared to be reduced in such order that herniation occurred.<sup>6,7</sup>

At present two concepts are elaborated in an attempt to meet the demands of an ideal mesh; good fibroblast ingrowth and anchorage at the fascial side and no adhesion formation at the peritoneal side. These concepts include a double-layer mesh, having a macroporous and a microporous or nonporous side, and a traditional mesh combined with an anti-adhesive agent either incorporated in the mesh or added separately in the peritoneal cavity. Double-layer meshes are increasingly applied in the clinical situation, but despite very encouraging experimental results, high mesh infection rate and decreased tensile strength at the mesh-tissue interface have been reported as well.<sup>3,8,9</sup> Mesh combined with anti-adhesives has good anchorage and shows significant reduction of adhesions in the experimental setting.<sup>4,5,10-12</sup>

We studied various types of anti-adhesive agents combined with a macroporous mesh and compared adhesion formation, herniation, and infection with standard and double-layer meshes in a rat model of large incisional hernia.

## materials and methods

### Animals

Male Wistar rats (Harlan, Zeist, The Netherlands), weighing between 165 g and 225 g were housed at 21°C with a day-night cycle of 12 hours. They had free access to water

and standard rodent chow (Hope Farms BV, Woerden, The Netherlands). Study protocols were approved by the Animal Ethics Review Committee of the Faculty of Medicine, Radboud University Nijmegen, The Netherlands.

### Meshes

Meshes used were polypropylene mesh (PPM) (Prolene, Ethicon, Johnson & Johnson Medical, Norderstedt, Germany), which served as control mesh, polypropylene/expanded-polytetrafluoroethylene mesh (PPM/e-PTFE) (Bard Composix, Bard, New Jersey, USA), polypropylene mesh/sodium hyaluronate/carboxymethylcellulose (PPM/HA/CMC) (Sepramesh, Genzyme Corporation, Cambridge, USA), and polypropylene-collagen/polyethylene-glycol/glycerol mesh (PPM-CPGG) (Parietene Composite, Sofradim International, Trévoux, France).

### Anti-adhesive agents

Anti-adhesive agents used were auto-cross-linked polymers (ACP) Gel (Hyalobarrier gel, Fidia Advanced Biopolymers srl, Abano Terme, Italy) and Fibrinogen glue (FG) (Tissucol, Baxter Healthcare Corporation, Deerfield, USA).

### Study design

Sixty rats were anaesthetized with an isoflurane (Abbott Laboratories Ltd., Queenborough, UK) nitrous-oxide oxygen mixture. After shaving and disinfection of the abdomen, a midline laparotomy was performed. Subsequently a 2 x 3 cm full thickness abdominal wall defect was created, which represents approximately 25% of the abdominal wall, without excision of the skin.<sup>7</sup> Rats were randomised in six treatment groups (Table 1). In group 1 (controls), the abdominal hernia was treated by using a PPM. In group 2 and 3 PPM was combined with use of the anti-adhesive agents ACP gel (group 2) and FG (group 3). In group 4-6, composite meshes were used; a mesh having a macroporous and a microporous side, consisting of polypropylene combined with e-PTFE (group 4), a mesh having a polypropylene layer combined with a hyaluronan-based anti-adhesive layer (group 5), and a mesh having a collagen-based anti-adhesive layer added to a polypropylene one (group 6). Meshes of 2.5 x 3.5 cm were placed using underlay technique and were sutured to the fascia with eight interrupted, non-resorbable 4/0 polypropylene (Prolene, Ethicon, Johnson & Johnson Medical) sutures. Four-millilitre ACP (4%) gel and 2 ml of FG were applied over the abdominal organs under the mesh, before the last two sutures were tied in group 2 and 3, respectively. The underlay technique was chosen because of claimed superiority preventing herniation above inlay or onlay techniques.<sup>13</sup> Skin was closed using iron staples.

table 1

Different treatment groups in an abdominal wall hernia model in rats.

Group	Rats (n)	Treatment	Separate anti-adhesive agent	Description
1	10	PPM	No	Control
2	10	PPM + ACP-gel	ACP-gel	Mesh + anti-adhesive
3	10	PPM + FG	FG	Mesh + anti-adhesive
4	10	PPM/e-PTFE	No	Double layer mesh
5	10	PPM/HA/CMC	No	Mesh including anti-adhesive
6	10	PPM/CPGG	No	Mesh including anti-adhesive

PPM = polypropylene mesh

ACP = auto-cross-linked polymers

FG = fibrinogen glue

e-PTFE = expanded-polytetrafluoroethylene

HA/CMC = sodium hyaluronate/carboxymethylcellulose

CPGG = collagen/polyethylene-glycol/glycerol

Mesh infection was thoroughly monitored in the post-operative period and at premature death. Mesh infection was defined as any pus discharge from the wound resulting in wound dehiscence and uncovered mesh. After two months, animals were killed using carbon dioxide asphyxiation. The abdomen was opened using a lateral incision, aside from the mesh. The presence of herniation was noted and the percentage of mesh covered by adhesions was scored. The severity of adhesion formation to the mesh was classified using the Zühlke criteria, whereby grade zero means no adhesions and grade 4 means very dense adhesions, only dissectable with sharp instruments with organ damage almost unavoidable.<sup>14</sup> Subsequently, the mesh including 1 cm of surrounding fascia was harvested. Sutures were removed and tensile strength of the mesh-fascia specimen was determined.



### Tensile testing

After collection of the mesh with surrounding tissue, the mesh was divided in two parts, leaving surrounding tissue on three sides. Subsequently the tissue on two sides was removed, and the width of the remaining mesh-tissue interface was measured (mm). Both ends of the mesh-tissue specimen were fixed in metal clips of a tensile tester (Instron, Canton, USA). Tension on the specimen was increased until rupture of the mesh-tissue interface or fascia itself occurred. Tests were performed with a rate of strain of 1 cm/min. Maximal tensile force was expressed in Newton per square mm of specimen.

### Statistical analysis

Statistical analysis between groups was performed using the Chi-squared test for independence for comparison of numbers of events, and the Kruskal-Wallis test (two-tailed) for comparison of continuous variables. The Kruskal-Wallis test was extended with post-tests in case of significant differences.  $P < 0.05$  was considered significant.

## results

### Mesh infection

The total number of animals that developed mesh infection was 6; one rat in the PPM/ACP group, three rats in the PPM/e-PTFE group and two rats in the PPM/CPGG group. Mesh infection led to premature death in one rat (PPM/CPGG group). Differences between groups were not significant ( $P = 0.114$ ) (Table 2).

### Adhesion formation

The percentage of the mesh covered by adhesions differed significantly between groups ( $P = 0.03$ ), with PPM/HA/CMC having the lowest percentage of adhesions (10%) (Table 2). Post-tests revealed that the difference in mesh coverage was significant for PPM/HA/CMC compared to control (PPM) ( $P < 0.05$ ). One rat in the PPM/HA/CMC group had zero adhesions. Severity of adhesion formation differed significantly between groups ( $P < 0.002$ ). Scores in the PPM/HA/CMC group (2, range 0-4) and PPM/ACP group (2, range 1-2) were significant lower than those in the PPM group (3, range 2-4;  $P < 0.05$  and  $P < 0.01$ , respectively) (Table 2). The number of animals having dense adhesions (grade 3 and 4) differed between groups ( $P < 0.002$ ). One rat

Table 2 Infection, adhesions, and herniation after abdominal wall reconstruction with different meshes in a rat model.

Mesh	Number of rats at end of study	Number of rats with infection	Percent of mesh covered by adhesions (median+range)	Zühlke score (median range)	Number of rats with Zühlke score 0-2 †	Number of rats with Zühlke score 3-4 †	Number of rats with herniation ‡
PPM	10	0	40 (10-80)	3 (2-4)	3	7	0
PPM/ACP	10	1	35 (15-90)	2 (1-2)**	10	0	5
PPM/FG	10	0	30 (5-90)	2 (2-3)	9	1	1
PPM/e-PTFE	10	3	22.5 (10-100)	3 (2-3)	4	6	0
PPM/HA/CMC	10	0	10 (0-35)*	2 (0-4)*	9	1	0
PPM/CPGG	9	2	40 (5-90)	2 (1-3)	6	3	0

\* $P < 0.05$  PPM/HA/CMC versus PPM  
 \*\* $P < 0.01$  PPM/ACP versus PPM  
 † $P < 0.002$  between groups  
 ‡ $P < 0.001$  between groups

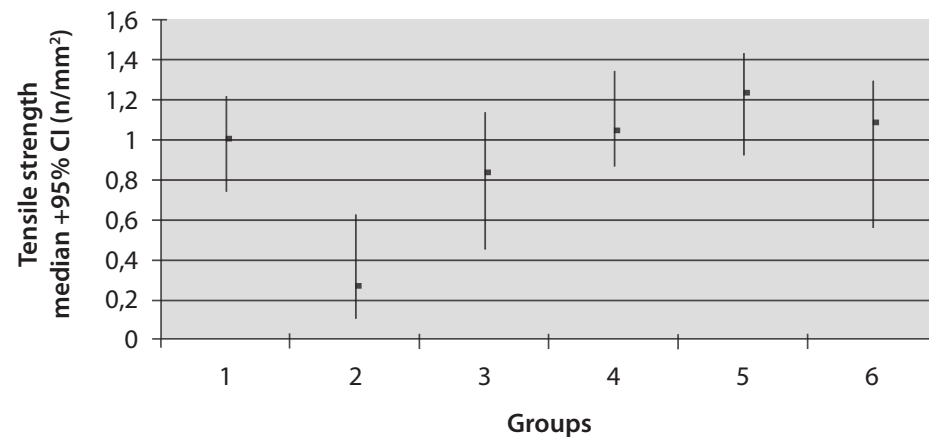
in the PPM/HA/CMC and in the PPM/FG group developed dense adhesions and zero rats in the PPM/ACP group (Table 2). Three PPM/e-PTFE rats with infection had 100% mesh coverage with dense adhesions (grade 3).

### Herniation and tensile strength

Herniation rate was significantly higher in PPM/ACP rats (50%) compared to PPM/FG rats (10%) and rats in all other groups (0%) ( $P < 0.001$ ) (Table 2).

The interfaces between fascia and PPM/HA/CMC had the highest tensile strength ( $P < 0.005$ ) (Figure 1). PPM/HA/CMC and PPM/e-PTFE mesh-fascia interfaces demonstrated significantly higher maximal tensile strength ( $P < 0.01$  and  $P < 0.05$ , respectively) than the PPM/ACP mesh-fascia interface.

Figure 1 Tensile strength mesh-fascia interface.  
Group 1: PPM, group 2: PPM/ACP, group 3: PPM/FG,  
group 4: PPM/e-PTFE, group 5: PPM/HA/CMC, group 6: PPM/CPGG



## discussion

Reconstruction of large incisional hernias, compelling the use of prosthetic material, is a challenge in general surgery. Mesh infection, adhesive bowel obstruction, fistula formation, and hernia recurrence are devastating early and late post-operative complications. Much research has focused on finding the ideal mesh preventing these complications. The ideal mesh should well incorporate fibrocollagenous tissue and anchor firmly to adjacent fascia, be unsusceptible for infection, and cause no adhesion formation. In the present study, PPM/HA/CMC approached the demands of an ideal mesh most, having superior anti-adhesive properties, good anchorage to the fascia, and no infection in this rat model of abdominal wall defect.

There are several animal models to investigate mesh repair of incisional hernia including rat, rabbit, and porcine model. No model has proven superiority mimicking the human situation. We choose rats because of our large experience with these animals and the reproducible model of incisional hernia repair and evaluation of adhesions.

HA/CMC has demonstrated experimental and clinical efficacy reducing post-operative adhesion formation in various types of abdominal-pelvic operations.<sup>15,16</sup> The adhesion reducing capacity is attributed to mechanical separation of injured serosal layers. A contributing biological effect of the hyaluronan component on peritoneal repair mechanisms has recently been suggested.<sup>17,18</sup> Encouraged by the good clinical results, investigators used a HA/CMC sheet underlying a PPM in incisional hernia repair, leading to a reduction of adhesion formation.<sup>4,10</sup> The composite mesh of PPM, coated on the peritoneal side with a hyaluronan-based bioresorbable membrane demonstrated similar adhesion reduction but does not exhibit the difficult handling characteristics like the separate HA sheet.<sup>5,11</sup> Adhesions that developed by using PPM/HA/CMC were not only reduced in number but were more filmy, which is of clinical importance reducing enteric fistula formation and inadvertent enterotomy on re-entry of the abdomen. More filmy adhesions were also seen to the other meshes that were combined with anti-adhesives. Nevertheless, this study did not reproduce the results of recent studies, in which the use of presumed anti-adhesive substances as fibrinogen, collagen, and hyaluronate gel, led to a marked reduction in amount and density of adhesions.<sup>8,12,19-24</sup> The PPM/e-PTFE with very small pore size at the peritoneal side was designed to withhold ingrowth of cells involved in adhesion formation and yet failed to do so. Massive dense adhesions to the meshes were particularly seen in three animals with a mesh infection, a finding similarly done in the two animals with an infected PPM/CPGG. Stimulation of the coagulation cascade by bacteria invading the mesh is a first step in fibrin deposition and adhesion formation. The overwhelming

inflammatory response accompanying infection stimulates exudation of fibrinogen-rich fluid in the peritoneal fluid and attracts peritoneal inflammatory cells, processes known to be key factors in adhesion formation.<sup>25,26</sup> An inflammatory response elicited by the foreign body as such, has been demonstrated with the use of e-PTFE and is a possible additional factor inducing adhesions.<sup>27</sup> With regard to prevention of adhesion formation to the mesh, the concept of preventing inflammation-induced fibrinous attachments and rapid coverage with mesothelial cells might be more valid than that of small pore size or no pores at all preventing cell ingrowth. Hyaluronate, present in ACP gel and PPM/HA/CMC has documented anti-inflammatory properties.<sup>17,18</sup> Use of fibrinolytic agents or mesothelial cell layers are alternatives preventing deposition of products following peritoneal inflammatory response.<sup>28,29</sup> Increased mesh infection in the present study is in concordance with the clinically known susceptibility of e-PTFE to bacterial invasion and outgrowth giving infection that almost always require mesh excision. This might be explained by the size of host defence cells, which prevents their penetration of the microporous e-PTFE structure, while bacteria, which are smaller in size, are able to invade the mesh.

Although auto-cross-linked hyaluronate showed great potential in reducing the density of adhesions to the PPM, the high rate of herniation makes it unsuitable for use in hernia repair. Protrusion of the visco-elastic substance when suturing the mesh to the fascial edges combined with the prolonged residence time may adversely affect the healing process at the mesh-fascia interface. Wound-healing problems reflected by fascial dehiscence or incisional hernia are not known from scarce data available on the gel.

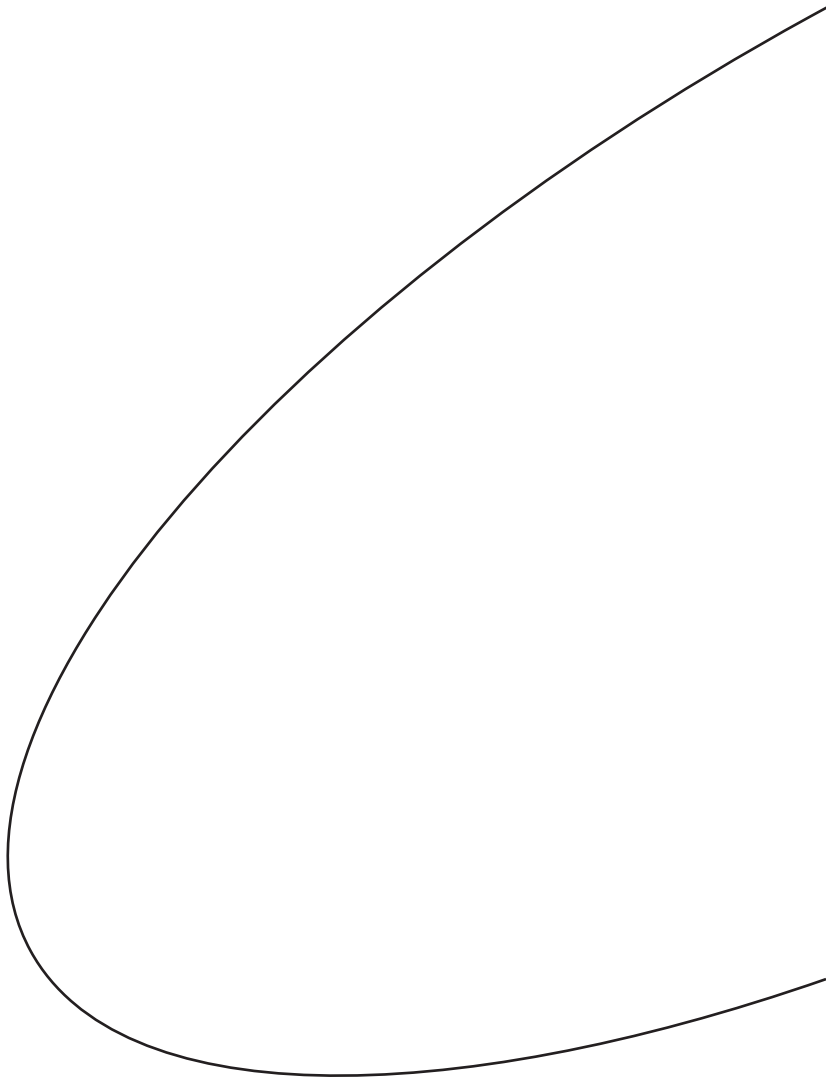
Fibrin glue has shown beneficial effects reducing adhesions attributed to rapid sealing of lymph and blood vessels at traumatized peritoneal surfaces preventing ongoing fibrinogen exudation.<sup>23,24</sup> In the present study, use of PPM/FG decreased adhesion density. The large clinical experience with fibrin glue in other surgeries and the easy handling of the spray form makes it an attractive alternative to HA/CMC in clinical hernia repair.

Although PPM/HA/CMC was superior to other composite meshes and PPM combined with anti-adhesives in this model, complete adhesion prevention was not achieved. Laparoscopic placement of the mesh could further decrease adhesion formation as laparoscopic surgery has been associated with diminished inflammatory reaction.<sup>30</sup> For laparoscopic use a more versatile material (Sepramesh IP, Genzyme Corporation) has recently been designed because the one used in the experiments cracks when applied through laparoscopic trocars.

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part 3



summary, general discussion  
and recommendations

**Part 1** of the thesis is dedicated to the “components separation technique” (CST) to repair (very) large midline abdominal wall defects. The technique was first described by Ramirez, Ruas and Dellon, in 1990.<sup>1</sup>

In **Chapter 1** the anatomy of the abdominal wall and the surgical technique of CST and its modifications are described in detail. The technique is based on translation of the muscular layers of the abdominal wall by subsequent transection of the external oblique muscle and the posterior rectus sheath. Special attention is paid to the anatomy of the blood supply of the ventral abdominal wall via the epigastric and intercostal arteries and the innervation of the musculature of the ventral abdominal wall.

In **Chapter 2** the results of a retrospective analysis of patients who underwent abdominal wall reconstruction with CST are presented. The early and late results of the technique were evaluated. The records of 43 patients, 11 women and 32 men, with mean age of 49.7 (range 22-78) were reviewed for body length and weight, size and cause of the hernia, intra- and post-operative mortality and morbidity. Special attention was given to wound and pulmonary complications. To determine reherniation, patients were invited to attend the outpatient clinic at least 12 months after repair for physical examination of the abdominal wall.

The hernias resulted from elective surgery in 19 patients and acute surgery in 24 patients. Eleven patients had a hernia after open treatment of generalized peritonitis and 13 patients had a recurrent hernia. One patient (2%) died on the sixth post-operative day from mesenteric thrombosis. The post-operative course was complicated in 17 patients (40%): fascial dehiscence in one, hematoma in five, seroma in two, wound infection in six, skin necrosis in one, and respiratory insufficiency in two. Thirty-eight patients (88%) were seen for follow-up, after a mean period of 15.6 months (range 12 to 30 months). Recurrent hernias were found in 12 of the 38 patients (32%). The remaining four patients had no recurrent hernia after 1, 1, 3 and 4 months respectively. It was concluded that CST is useful for the reconstruction of large abdominal wall hernias, although morbidity and reherniation rates are high.

In **Chapter 3** the techniques used for autologous repair of incisional hernias and abdominal wall defects were reviewed. Medline and PubMed databases were searched for English or German publications concerning autologous repair of abdominal wall hernias and defects that could not be closed primarily using the following keywords: “components separation technique” (CST), Ramirez (technique), da Silva (technique),



(tensor) fascia(e) lata(e), latissimus dorsi, rectus femoris, myocutaneous flap, ((auto) dermal) graft, dermoplasty, cutisplasty, hernia and abdominal wall defect, or combinations. The publications were analyzed for methodological quality using the MINORS-index and data were abstracted concerning surgical technique, mortality, morbidity and reherniation. It was found that CST is the best documented technique for autologous repair of incisional hernias. The procedure has a high morbidity rate, 24% wound complications and 18% recurrences. Although the results of the da Silva technique are good (morbidity 5-20%; reherniation 0-3%), the poor methodological quality of the studies precludes the drawing of firm conclusions. Autologous repair with free tissue grafting with either fascia lata or dermal grafts is an attractive alternative if the aforementioned techniques cannot be used, but wound complications are found in 42% and recurrent hernias in up to 29% of patients. Pedicled or free vascularized flaps are reserved for the very complex cases where free grafts cannot be used and reconstructions must be performed with vascularized tissue.

In **Chapter 4** the results of a randomized controlled clinical trial are presented. Patients with large midline abdominal wall hernias were randomized for CST or prosthetic repair (PR) using an expanded-polytetrafluoroethylene double layer patch impregnated with silver salts and chlorhexidine (Gore-Tex dual mesh plus with holes, W.L. Gore and associates Inc., Flagstaff, Arizona, USA). All patients were operated on in a standardized way. Post-operative morbidity was scored on a standard form and patients were regularly seen during 36 months after operation to determine recurrent hernia. Between November 1999 and June 2001, 39 patients were randomized, 19 for CST and 18 for PR. Two patients were excluded per-operatively because of gross contamination of the operative field. There were no differences between the groups at baseline with respect to demographic details, co-morbidity, and size of the defect. There was no in-hospital mortality. Wound complications were found in 10 of 19 patients after CST and 13 of 18 patients after PR. Seroma was found more frequent after PR. In 7 of 18 patients after PR, the prosthesis had to be removed as a consequence of early or late infection. Reherniation occurred in 10 patients after CST and in 4 patients after PR. It was concluded that repair of abdominal wall hernias with the CST compares favourably with prosthetic repair. Although the reherniation rate after CST is relatively high, the consequences of (minor) wound healing disturbances in the presence of e-PTFE patch were substantial, often resulting in loss of the prosthesis.

In **Chapter 5** an endoscopically assisted “components separation technique” is described in order to prevent wound healing disturbances by reducing the wound surface and to spare the blood supply to the skin of the ventral abdominal wall. The technique was used in 5 patients with an enterostomy. In these patients no wound complications occurred and all enterostomies functioned well after the reconstruction.

**Part 2** of the thesis is dedicated to prosthetic repair of incisional hernias.

**Chapter 6** describes a retrospective study comparing three different techniques for abdominal wall reconstruction using polypropylene mesh (PPM), onlay, inlay, and sublay.

The records of 53 consecutive patients with large midline incisional hernias, 25 women and 28 men, mean age 60.4 (range 28-94), were reviewed. Polypropylene mesh was implanted using the onlay technique in 13 patients, inlay in 23 patients and sublay in 17 patients. Either the greater omentum or a polyglactin mesh was interponated between the mesh and the viscera. The records of these 53 patients were reviewed with respect to size and cause of the hernia, per- and post-operative mortality and morbidity with special attention to wound complications. Patients were invited to attend the outpatient clinic at least 12 months after implantation of the mesh for physical examination of the abdominal wall. Post-operative complications occurred in 14 (26.4%) patients. The onlay technique had significantly more complications, as compared to both other techniques. Reherniation occurred in 15 (28.3%) patients. The reherniation rate of the inlay technique was significantly higher than the sublay technique (44% versus 12%,  $P = 0.03$ ), and tended to be higher than the onlay technique (44% versus 23%,  $P = 0.20$ ). It was concluded that sublay repair with PPM seems to be better than inlay and onlay repair.

Expanded-polytetrafluoroethylene (e-PTFE) is an attractive biomaterial to repair large abdominal wall hernias, especially in cases where interposition of peritoneum or greater omentum between prosthesis and bowels is impossible. However, infection and seroma formation are major drawbacks, as described in Chapter 4. To reduce the risk of infection, an e-PTFE patch impregnated with chlorhexidine and silver salts has been manufactured (Gore-Tex dual mesh plus with holes, W.L. Gore and associates Inc., Flagstaff, Arizona, USA) (e-PTFE DL-plus patch). In **Chapter 7** an experimental study was performed to determine whether impregnation with silver salts and chlorhexidine affects biocompatibility, herniation rate and adhesion formation. In vitro, the release of silver salts from e-PTFE DL-plus patch was determined in demineralized water and cytotoxic effects were determined in fibroblast cultures. It was found that toxic  $\text{Ag}^+$  concentrations in the supernatant were reached within 24 hours. Fibroblast cultures showed an inhibiting zone around the e-PTFE DL-plus patch and a significant decreased proliferation rate as compared to a control e-PTFE patch without silver salts and chlorhexidine (e-PTFE DL patch).

Subsequently, in 30 Wistar rats, abdominal wall defects were created and reconstructed with either an e-PTFE DL-plus patch or an e-PTFE DL patch. The rats were

sacrificed after 2 months and autopsy was performed to determine the inflammatory response around the patch, ingrowth of fibrocollagenous tissue into the patch, herniation rate and adhesion scores. One rat in each group died within the first week post-operatively due to massive herniation and strangulation of bowel. None of the rats developed wound complications. At microscopy, no ingrowth of fibrocollagenous tissue into both patches was found, on either side of the prosthesis. In contrast with the non-impregnated patch, the e-PTFE DL-plus patch showed massive infiltration of granulocytes in the surrounding fat tissue and fat necrosis. The herniation rate tended to be higher in the e-PTFE DL-plus group (80%) than in the e-PTFE DL group (53%) ( $P = 0.06$ ,  $X^2$ -test, single sided). The median adhesion score in the e-PTFE DL patch group (1, range 0-2) was comparable to that in the e-PTFE DL-plus group (2, range 1-3). It was concluded that impregnation with silver salts makes the e-PTFE DL-plus patch less biocompatible.

The use of intra-peritoneal polypropylene mesh (PPM) to repair incisional hernia carries the risk of adhesion formation and damage to the intra-abdominal viscera. Polyglactin 910 mesh (PGM) is a resorbable mesh, often used as a barrier between PPM and the intra-abdominal viscera. In **Chapter 8** an experimental study in rats was performed to determine if interposition of a PGM between the PPM and viscera alters biocompatibility, adhesion formation and herniation. In 80 rats a 2 x 3 cm abdominal wall defect was created. Rats were randomly assigned into two groups of 40 rats in which the defect was repaired with an 2.5 x 3.5 cm prosthesis of either PPM or PPM plus polyglactin 910 mesh (PPM-PGM). Ten rats were sacrificed at 1, 2, 3, and 6 months respectively and autopsy was performed to determine herniation and adhesion rates. Samples of the mesh-fascia interface were taken for histology.

In the PPM group, one rat died. No hernias were found after 1, 2, and 3 months. At 6 months one of the 9 rats had a hernia. In the PPM-PGM group, two rats died. Two rats had a hernia after 1 month and 3 rats after 6 months. The adhesion score in the PPM group (median 3, range 2-3) did not differ from the score in the PPM-PGM group (median 3, range 2-3) at 1, 2, 3, and 6 months. Histology revealed a capsule of fibrocollagenous tissue around the PP fibres, which matured over months. In both groups, an inflammatory response around the prosthesis was found in the first month. The inflammatory response around the prosthesis was more outspoken in the PPM-PGM group than in the PPM group. It was concluded that interposition of PGM between PPM and viscera does not alter adhesion formation nor influences herniation rate.

In **Chapter 9** various anti-adhesives and mechanical barriers were tested to prevent adhesion of omentum and bowels to PPM. In 60 Wistar rats an abdominal wall defect of 2 x 3 cm was created. Rats were randomly assigned in six groups of 10 rats. The defects

were repaired with PPM (control), PPM with auto-cross-linked polymers (ACP) gel, PPM with fibrinogen glue (FG), polypropylene/expanded-polytetrafluoroethylene (e-PTFE) mesh, polypropylene coated with sodium hyaluronate/carboxymethylcellulose (HA/CMC) mesh, or polypropylene-collagen coated with polyethylene-glycol/glycerol (CPGG) mesh. After implantation the wounds were inspected daily during the first two weeks. After two months, the rats were sacrificed to determine adhesion scores, herniation and tensile strength of the mesh-tissue interface. Six rats had a mesh infection; three in the PPM/e-PTFE group, two in the PPM/CPGG group and one in the PPM/ACP group. Adhesion scores in the PPM/HA/CMC group and PPM/ACP group were significantly lower compared to the control (PPM) group. The herniation rate in the PPM/ACP group was significantly higher than in the other groups. Mean tensile strength 1.2 N/mm<sup>2</sup> (95% CI 0.9-1.4 N/mm<sup>2</sup>) of the mesh-tissue interface in the PPM/HA/CMC group was significantly higher than in the other groups ( $P < 0.005$ ). It was concluded that PPM/HA/CMC approaches the demands of the ideal mesh, having superior anti-adhesive properties, no herniation and good anchorage to the fascia.

## general discussion

Reconstruction of large midline abdominal wall hernias still is a challenge for surgeons. Since primary closure of the abdomen in large midline abdominal wall hernias is not feasible, the fascial gap must be bridged by autologous or prosthetic material. Several techniques are available for abdominal wall reconstruction with either autologous or prosthetic material. Autologous repair is attractive especially in the presence of contamination or infection. Several techniques using the patients own tissues have been described, as reviewed in **Chapter 3**. Most information available concerns the "components separation technique" (CST). CST is an attractive, relatively easy technique, but morbidity and (re)herniation rates are high.

Seroma formation and wound infection are the main post-operative complications after CST.<sup>2,3</sup> Wound complications are found in about 24% of patients, but the incidence varies widely in the literature.<sup>4</sup> Probably the incidence of wound complications is underestimated since most studies are retrospective and wound surveillance protocols are mentioned in a minority of studies.<sup>4</sup> The extensive dissection and consequently the large subcutaneous wound surface in combination with transection of the perforating branches of the epigastric artery, supplying the skin of the ventral abdominal wall, are probably important factors responsible for disturbed wound healing.



Lowe et al. and Saulis et al. applied CST but saved the peri-umbilical perforating arteries.<sup>5,6</sup> They claimed that this modification prevents skin necrosis. As described in **Chapter 5**, we further modified the technique by developing an endoscopically assisted, minimal invasive technique to perform CST. The technique limits subcutaneous dissection and saves the blood supply of the skin. The preliminary results are very promising but the experience is still limited. Several clinics in the United States of America have adopted the technique, but the number of patients treated is small and results have not been published thus far. Therefore the results of larger patient series consisting of consecutively included patients are eagerly awaited. Finally prospective randomized trials to compare these new techniques with the original technique are warranted.

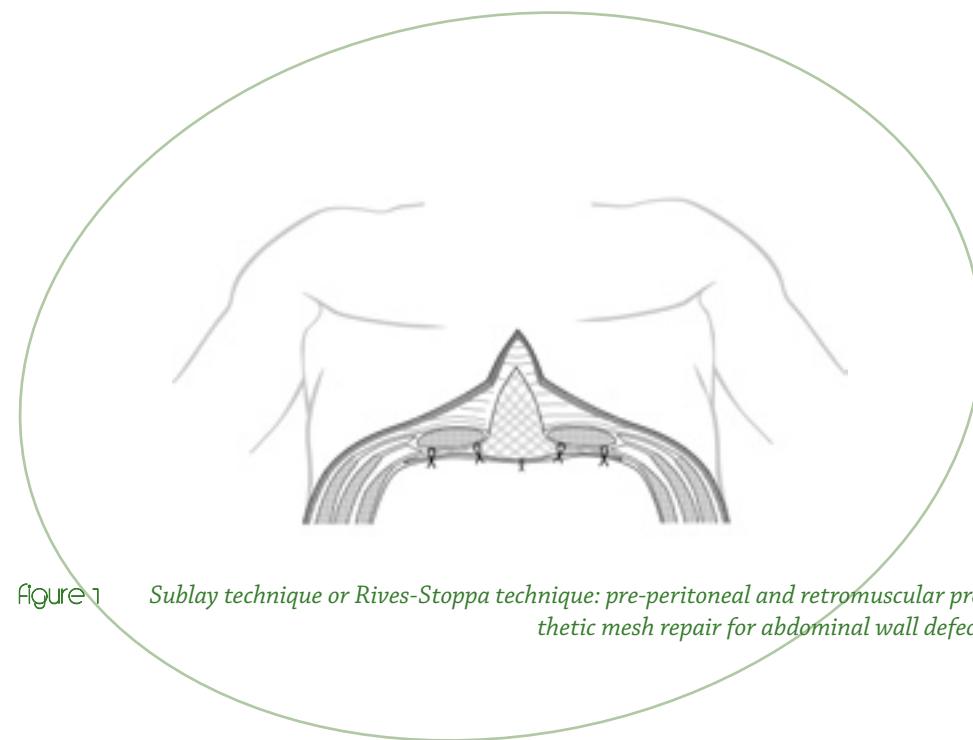
The relatively high reherniation rate after CST of 18%, as reported in the literature, after a follow-up of at least one year, is another disadvantage (**Chapter 3**). Since follow-up is poorly defined in most studies, the reherniation rate is probably higher. Reherniation rate was 32% after a follow-up of 12 months or more in 43 patients operated in five Dutch hospitals (**Chapter 2**). All these patients were seen by one surgeon in the outpatient clinic. In a prospective randomized multi-center clinical trial, reherniation rate was even 50% (**Chapter 4**). Similar results are reported after suture repair of incisional hernias.<sup>7,8,9</sup>

Probably the results of abdominal wall repair can be improved by using biomaterials either to bridge the fascial gap or to reinforce the fascia after primary closure. However, in a prospective randomized multi-center trial the results of CST proved to be better than after prosthetic repair, because prosthetic infection as a result of seroma formation, skin necrosis and wound infection, resulted in loss of the prosthesis in 7 of 18 patients (**Chapter 4**). If prosthetic material is used to bridge the fascial defect, the prosthesis is only covered by the skin and the subcutaneous tissue. The risk of prosthetic infection is high since even minor wound healing disturbances, which often occur in these patients, will result in prosthetic infection. Better results are reported after pre-peritoneal and retromuscular positioning of the prosthesis following the technique of Rives-Stoppa (Figure 1).<sup>10</sup>

If wound complications occur in small abdominal wall hernias, the prosthesis remains covered with viable muscles thus preventing infection of the prosthesis. In a recent prospective randomized multi-center trial, comparing Rives-Stoppa repair of midline incisional hernias with either heavy or light weight mesh, reherniation rates of 7 and 17% respectively were reported.<sup>11</sup> Several retrospective studies report similar results after Rives-Stoppa repair of incisional hernias.<sup>7-15</sup> Based on our experience and the reports on pre-peritoneal or retromuscular prosthesis it is reasonable to assume that a

combination of CST with a pre-peritoneal and retromuscular prosthesis improves the results of CST alone. It combines the cosmetic and functional advantages of restoration of the anatomy of the ventral abdominal wall with the good results of prosthetic repair. In 2004, a prospective randomized controlled multi-center clinical trial (RAPP trial) was initiated to compare the original CST with a combined CST/Rives-Stoppa repair.

Several prosthetic materials have been developed for hernia repair. The ideal prosthetic material must have conflicting properties. On one hand, the prosthesis must anchor to the adjacent fascia by ingrowth of fibrocollagenous tissue into the prosthesis. On the other hand, adhesions from the intra-abdominal viscera to the prosthesis must be prevented. Polypropylene mesh still is the most often used material, which suffices well in most patients. PPM is less suitable in patients with (very) large her-



**Figure 1** *Sublay technique or Rives-Stoppa technique: pre-peritoneal and retromuscular prosthetic mesh repair for abdominal wall defects.*

nia, since peritoneum and/or greater omentum to interpose between the bowels and the mesh is often lacking. The majority of the surgeons are reluctant to implant PPM in direct contact with the bowels.

In the last decades prosthetic materials have been developed for intra-abdominal implantation. Expanded-polytetrafluoroethylene (e-PTFE) is one of these materials. E-

PTFE is often used as an alternative for PPM, for intra-abdominal reconstructions. E-PTFE is a soft, pliable and a highly hydrophobic prosthetic material. The microporous e-PTFE patch does not allow ingrowth of fibrocollagenous tissue, resulting in significantly less adhesions compared to PPM.<sup>16</sup> However, insufficient anchorage, due to lack of ingrowth of fibro-collagenous tissue results in a high reherniation rates in (pre)-clinical studies.<sup>16,17</sup> In clinical observational studies the reherniation rate varies between 0 and 50%.<sup>3,18-27</sup> Moreover, hydrophobicity makes the prosthesis susceptible to infection.<sup>28</sup> Prosthetic infection resulting in removal of the patch is reported in 2 to 38% of patients in clinical studies.<sup>3,18-30</sup> To diminish the risk of infection an e-PTFE patch impregnated with silver salts and chlorhexidine (Gore-Tex dual mesh plus with holes, W.L. Gore and associates Inc., Flagstaff, Arizona, USA) has been manufactured. This patch was used in a prospective randomized controlled clinical trial comparing CST with prosthetic repair. As mentioned, in 7 of the 18 patients the patch became infected, as a consequence of wound complications including partial skin necrosis and seroma (**Chapter 4**). In an experimental study the patch was to be found less biocompatible than the non-impregnated e-PTFE patch (**Chapter 7**). Although e-PTFE patches suffice well in laparoscopic hernia repair,<sup>31</sup> the patch is less suitable for the repair of large abdominal wall defects.

Implantation of large heavy weight PPM changes the physical properties of the abdominal wall which may result in pain and stiffness.<sup>32-34</sup> Other modifications of the original heavy weight PPM have been manufactured, to reduce the amount of polypropylene implanted in abdominal wall reconstruction. However in a recent randomized clinical trial Rives-Stoppa reconstruction with a light weight mesh resulted in an increased reherniation rate, although the difference was not statistically significant.<sup>11</sup>

Adhesion formation will remain a serious problem when polypropylene stays in contact with the bowels especially if the patient is re-operated.<sup>35</sup> The simplest technique of protection of the viscera is interposition of a resorbable polyglactin 910 mesh (PGM) between the bowel and the PPM. However, in an experimental study in rats we found that PGM does not prevent adhesion formation of PPM to bowels (**Chapter 8**). Similar observations were done in an experimental study using light weight polypropylene mesh mixed with polyglactin (Vypro mesh, Ethicon, Johnson & Johnson Medical, Norderstedt, Germany) and light weight polypropylene-polydioxanone composite with an oxidized cellulose coating (Proceed mesh, Ethicon, Johnson & Johnson Medical, Norderstedt, Germany).<sup>36-40</sup>

The newly designed prosthetic materials are based on mechanical separation or by chemical anti-adhesives of PPM and the bowels. In two recently performed experimental studies, polypropylene mesh coated with carboxymethylcellulose-sodium hy-

aluronate (Sepramesh, Genzyme Corporation, Cambridge, USA) was found to be superior to polypropylene coated with collagen/polyethylene-glycol/glycerol (Parietene Composite mesh, Sofradim International, Trévoux, France) and polypropylene coated with e-PTFE (Bard Composix mesh, Bard, New Jersey, USA) with respect to adhesion formation. Polyester with collagen/polyethylene-glycol/glycerol coating (Parietex Composite mesh, Sofradim International, Trévoux, France) gave similar results compared to the Parietene Composite mesh.<sup>39-42</sup> Clinical data on different PPM based prosthesis with respect to adhesion formation and reherniation are lacking. Randomized clinical trials, comparing these meshes using clinical outcome parameters, should therefore be performed.

## recommendations

Repair of incisional hernias in the midline is largely based on studies with a low level of evidence or even expert opinion. Numerous techniques have been advocated but prospective and randomized trials are scarce. Under clean or clean contaminated conditions, mesh repair of incisional hernias gives far better results than primary closure without further support (suture repair) (level of evidence 1b).<sup>7-15</sup> Pre-peritoneal retromuscular implantation of the mesh is preferred over implantation as an inlay or onlay (level of evidence 3b).<sup>15,35,43-54</sup> The choice of mesh depends on experimental data. Clinical data about the long term results behaviour of mesh are merely lacking.

Hardly any information is available about mesh repair in a contaminated or dirty environment. In general, biomaterials must not be used under these conditions because of the risk of chronic infection and extrusion of the mesh. Primary closure or CST repair are therefore the methods of choice under these conditions, although the reherniation rate will be high.

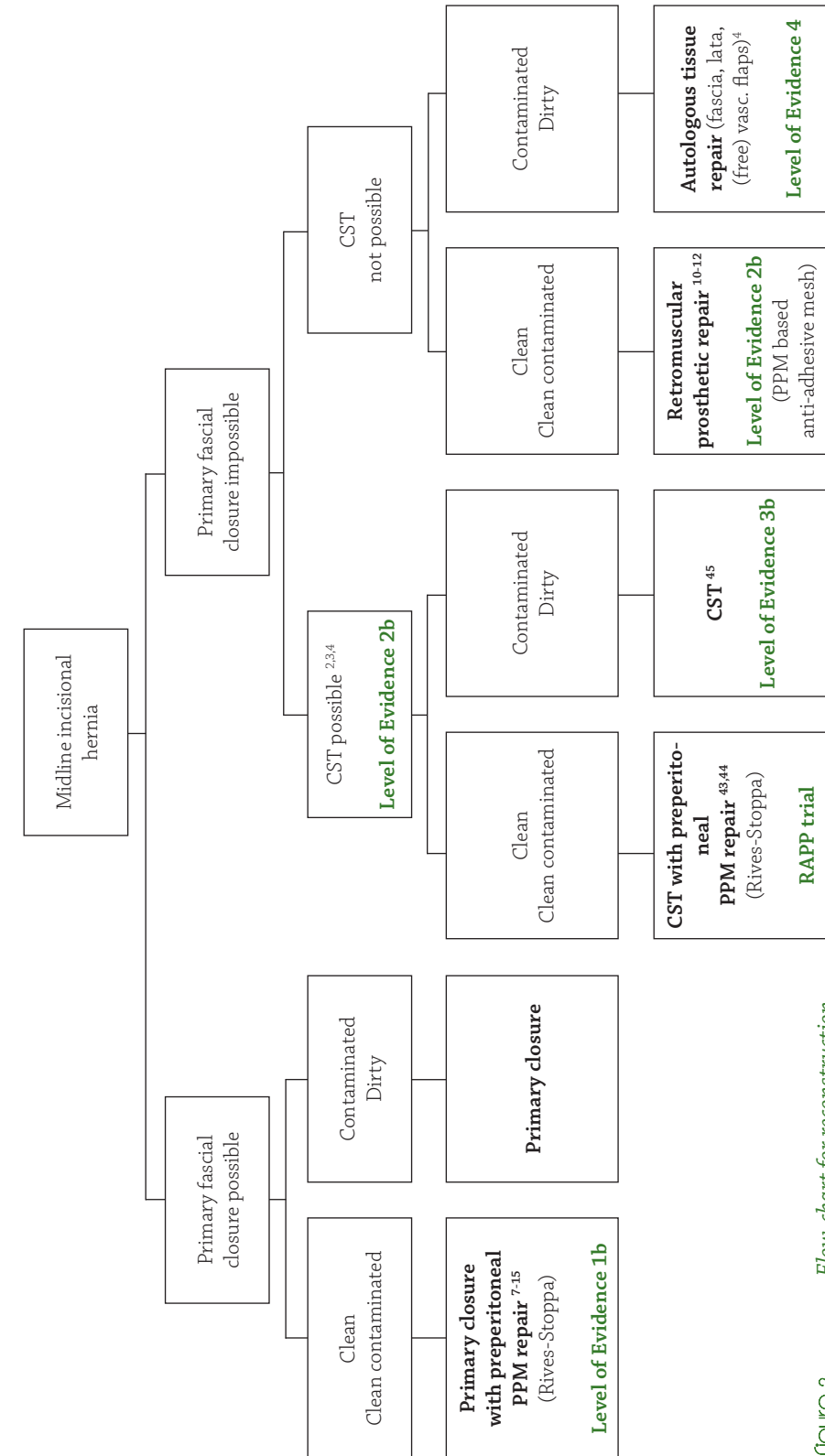
Based on the studies performed in this thesis and the available literature, a flow-chart for the repair of large abdominal wall hernias in the midline is made (Figure 2). The choice which technique must be used mainly depends on two factors. First, the possibility for primary closure of the fascia and second the grade of contamination of the surgical wound.

If primary closure of the fascia is possible, repair with a pre-peritoneal retromuscular placed PPM (Rives-Stoppa) is preferred, under clean or clean-contaminated condition.<sup>7-15,43</sup> Since no proper data are available about the results of meshes in a contami-

nated or dirty environment the use of mesh is discouraged. Therefore primary fascial closure without mesh is advised in a contaminated or dirty environment, accepting a recurrence rate of up to 50%.<sup>7-9,43</sup>

If primary fascial closure is not possible, CST is the preferred treatment to bridge the fascial gap (level of evidence 2b).<sup>2,3,4</sup> Probably a combination of CST with pre-peritoneal mesh will give the best results. This is suggested by the results of Dibello and Lowe using this technique in a part of their patients.<sup>55,56</sup> However proper evidence is lacking until the results of the prospective randomized multi-center study (RAPP-trial) comparing CST alone with CST plus pre-peritoneal polypropylene mesh repair will be available. Under contaminated or dirty conditions a plain CST is advised for the same reasons as mentioned above (level of evidence 3b).<sup>57</sup> If CST is impossible prosthetic repair is the method of choice, if the mesh can be covered by full thickness skin (level of evidence 2b).<sup>10-12</sup> The mesh should be placed in an intra-abdominal retromuscular position with sufficient overlap to the fascia. If mesh repair is contraindicated, autologous repair with free fascia lata graft, pedicled or free vascularized tensor fasciae latae flap is advised (level of evidence 4-5).<sup>4</sup> The combination of mesh covered with a pedicled omental flap (the omental sandwich technique) is an attractive alternative under these circumstances.<sup>58</sup>

If the peritoneum can not be closed between mesh and viscera intra-abdominal retromuscular reconstruction is needed. The choice of mesh for these reconstructions can only be based on clinical data with intermediate to low level of evidence or experimental data. An e-PTFE patch is contraindicated due to the high patch failure rate caused by infection (level of evidence 2b), although the reherniation rate is not different from PPM (level of evidence 3b).<sup>3,18-30</sup> Most data are available about heavy weight polypropylene mesh (PPM). Anchorage to the adjacent fascia is good, but adhesion formation is a major drawback. Therefore PPM is less suitable when the prosthesis comes into contact with the bowels.<sup>35</sup> In experimental studies the modifications of PPM with chemical anti-adhesive properties like: cellulose, hyaluronate or glycerol coating gave better results compared to the mechanical barrier, like polyglactin mesh or e-PTFE. For intra-abdominal retromuscular reconstruction, one of these polypropylene based meshes with chemical anti-adhesive properties (Proceed mesh, Sepramesh or Parietene composite mesh) should be used although clinical trials are lacking.<sup>39-42</sup>



**Figure 2** Flow-chart for reconstruction of midline abdominal wall hernias. (PPM= polypropylene mesh, CST= Components Separation Technique)

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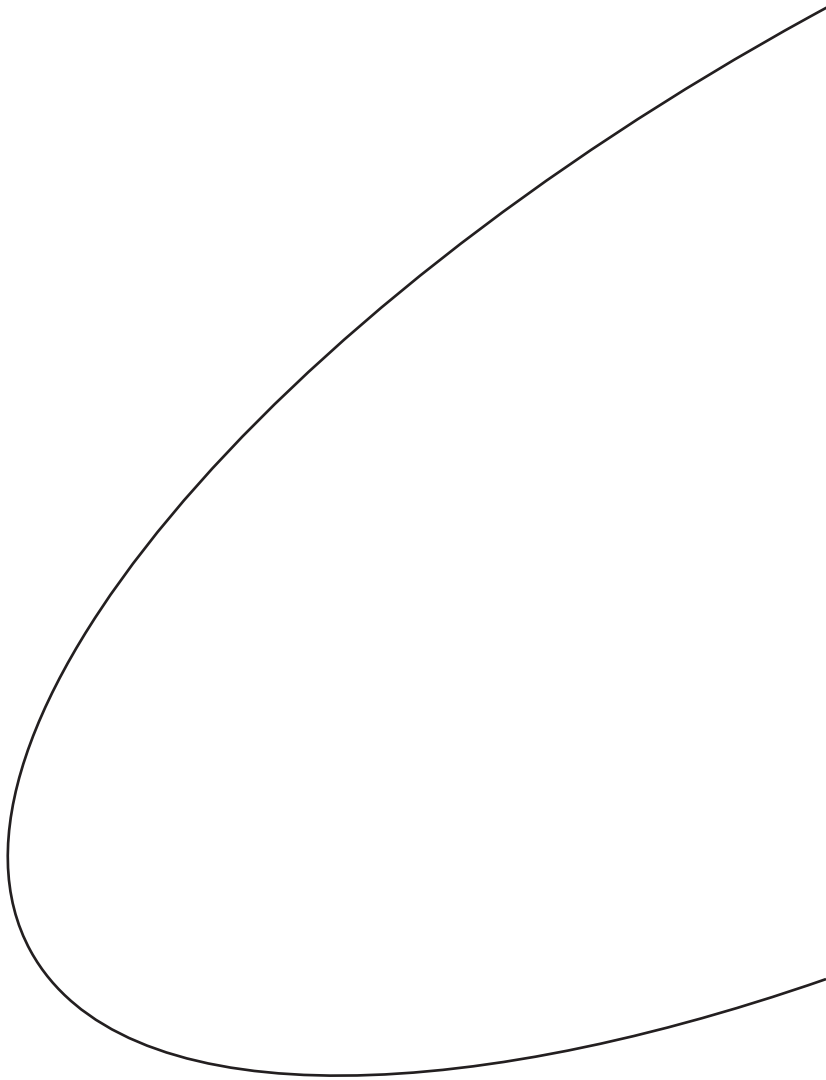
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11

samenvatting, discussie  
en aanbevelingen

**Deel 1** van dit proefschrift gaat over de “componenten separatie techniek” (CST) om (zeer) grote littekenbreuken te reconstrueren. Ramirez, Ruas en Dellon, waren in 1990 de eersten die deze techniek beschreven.<sup>1</sup>

In **Hoofdstuk 1** wordt de anatomie van de buikwand en de chirurgische techniek van de CST, inclusief alle modificaties, in detail beschreven. Deze techniek is gebaseerd op het scheiden van de verschillende spierlagen van de buikwand door het klieven van de insertie van de musculus obliquus externus aan de musculus rectus abdominis. Tevens wordt de posterieure rectus fascia gemobiliseerd. Verder wordt de vascularisatie en innervatie van de buikwand beschreven.

In **Hoofdstuk 2** worden de resultaten beschreven van een retrospectieve studie van patiënten die een buikwandreconstructie volgens de CST ondergingen. De vroege en lange termijn resultaten werden geëvalueerd. Uit de medische dossiers van 43 patiënten, 11 vrouwen en 32 mannen, met een gemiddelde leeftijd van 49,7 jaar (spreiding 22-78 jaar) werden de volgende factoren geëxtraheerd: lichaamslengte en gewicht, maten en oorzaak van het buikwanddefect, en per- en post-operatieve morbiditeit en mortaliteit. Er werd speciaal gelet op post-operatieve wond en pulmonale complicaties. Alle patiënten werden minimaal 12 maanden na de operatie uitgenodigd op de polikliniek heelkunde voor lichamelijk onderzoek om een recidief littekenbreuk te kunnen opsporen.

Bij 19 patiënten ontstond de breuk na een geplande laparotomie, bij 24 patiënten na een acute buikoperatie. Elf patiënten hadden een buikwanddefect na een ‘open buik’ behandeling voor gegeneraliseerde peritonitis. Dertien patiënten waren reeds eerder behandeld voor een buikwanddefect. Eén patiënt (2%) overleed op de zesde dag na operatie ten gevolge van mesenteriaal thrombose. Bij 17 patiënten (40%) was het post-operatieve beloop gecompliceerd: bij één patiënt was er sprake van fascie dehiscentie, bij vijf patiënten ontstond er een hematoom, bij twee patiënten was er seroomvorming, bij zes patiënten ontstond er een wondinfectie, in één patiënt trad er huidnecrose op, en een patiënt werd respiratoir insufficiënt. Achtendertig patiënten (88%) werden na gemiddeld 15,6 maanden (spreiding 12-30 maanden) gezien voor controle. Bij 12 van de 38 patiënten (32%) werd een recidief littekenbreuk vastgesteld. De vier overige patiënten hadden bij een vervolgcontrole, respectievelijk 1, 1, 3 en 4 maanden na de operatie, geen recidief littekenbreuk. Er werd geconcludeerd dat CST bruikbaar is voor de reconstructie van grote buikwanddefecten, ondanks de hoge morbiditeit en het hoge recidiefpercentage.

In **Hoofdstuk 3** worden de in de literatuur beschreven resultaten van de verschillende technieken voor reconstructie van grote littekenbreuken met autoloog materiaal beschreven. In de Medline en Pubmed databases werd gezocht naar Engels- of Duitstalige publicaties over grote littekenbreuken die niet primair te sluiten waren en gereconstrueerd werden met lichaamseigen materiaal. Hiervoor werden de volgende sleutelwoorden gebruikt: components separation technique (CST), Ramirez (technique), da Silva (technique), (tensor) fascia(e) lata(e), latissimus dorsi, rectus femoris, myocutaneous flap, ((auto) dermal) graft, dermoplasty, cutisplasty, hernia en abdominal wall defect, of combinaties. Van de geselecteerde publicaties werd de methodologische kwaliteit bepaald met behulp van de MINORS-index en gegevens over chirurgische techniek, mortaliteit, morbiditeit en recidief werden geëxtraheerd. CST is de meest uitgebreid beschreven techniek voor de reconstructie met lichaamseigen materiaal. De techniek kent een hoge morbiditeit: gemiddeld 24% wondcomplicaties en 18% recidief. Hoewel de resultaten van de da Silva techniek goed zijn (morbiditeit 5-20%, recidief 0-3%), kunnen er op basis van de matige methodologische kwaliteiten van de studies geen harde conclusies worden getrokken. Autologe reconstructie met vrij weefsel in de vorm van fascia lata graft of huid graft is een alternatief als CST of de da Silva techniek niet mogelijk zijn, maar gaat gepaard met 42% wondcomplicaties en 29% recidief. De gesteelde of vrij gevasculariseerde huidspierflap zouden gereserveerd moeten blijven voor de zeer complexe patiënten waarbij de andere technieken niet kunnen worden toegepast en er behoefte is aan een reconstructie met gevasculariseerd weefsel.

In **Hoofdstuk 4** worden de resultaten van een prospectief gerandomiseerde multicenter studie gepresenteerd. Patiënten met grote mediane buikwanddefecten werden gerandomiseerd tussen reconstructie met behulp van de CST of met een expanded-polytetrafluoroethyleen double layer patch geïmpregneerd met zilverzouten en chloorhexidine (PR) (Gore-Tex dual mesh plus with holes, W.L. Gore and associates Inc., Flagstaff, Arizona, USA). Alle patiënten werden geopereerd op een gestandaardiseerde wijze. De post-operatieve morbiditeit werd gescoord op een standaardformulier en patiënten werden frequent op de polikliniek gezien gedurende 36 maanden om recidiefbreuken vast te kunnen stellen. Van november 1999 tot en met juni 2001 werden 39 patiënten gerandomiseerd, 19 voor CST en 18 voor PR. Twee patiënten werden geëxcludeerd in verband met ernstige contaminatie tijdens de operatie. Er waren geen verschillen tussen de groepen ten aanzien van demografische gegevens, co-morbiditeit, en grootte van het defect. Er was geen post-operatieve sterfte binnen 30 dagen. Wondcomplicaties traden bij 10 van de 19 patiënten na CST op en bij 13 van de 18 patiënten na PR. Seroomvorming werd vaker gezien na PR. Bij 7 van de 18 patiënten na PR moest de patch worden verwijderd in verband met vroege of late infectie van de patch. Reherniatie trad op bij 10 patiënten na CST en bij 4 patiënten na

PR. Geconcludeerd werd dat de reconstructie van grote buikwanddefecten met behulp van CST aantrekkelijker is dan met een kunststof patch. Ondanks het relatief hoge recidiefpercentage na CST, zijn de gevolgen van (kleine) wondgenezingsstoornissen in de aanwezigheid van een e-PTFE patch groot, aangezien deze gepaard gaan met een reële kans op infectie, waardoor de patch verloren gaat.

In **Hoofdstuk 5** wordt de endoscopisch-geassisteerde CST beschreven. Deze endoscopisch-geassisteerde CST is ontwikkeld om het wondoppervlak te verkleinen, de bloedvoorziening van de huid te sparen en daarmee de kans op wondgenezingsstoornissen te verkleinen. De techniek werd gebruikt bij 5 patiënten met een stoma. Bij deze patiënten traden na de operatie geen wondcomplicaties op en bleven de stoma's goed functioneren.

**Deel 2** van dit proefschrift is gewijd aan de reconstructie van grote littekenbreuken met behulp van kunststof materiaal.

In **Hoofdstuk 6** worden de resultaten beschreven van een retrospectieve studie naar drie verschillende operatietechnieken voor reconstructie van grote mediane buikwanddefecten met behulp van polypropyleen mesh (PPM), gepositioneerd als onlay, inlay of sublay. De medische dossiers van 53 patiënten met grote mediane buikwanddefecten, 25 vrouwen en 28 mannen, gemiddelde leeftijd 60,4 jaar (spreiding 28-94 jaar) werden geanalyseerd. Bij 13 patiënten werd de buikwand gereconstrueerd met behulp van een onlay PPM, bij 23 patiënten met een inlay en bij 17 patiënten met een sublay. Het peritoneum, omentum of een polyglactin mesh werd gepositioneerd tussen de PPM en de darmen, om de darmen te beschermen tegen adhesievorming. Uit de medische dossiers werden de oorzaak en grootte van het buikwanddefect en de per- en post-operatieve mortaliteit en morbiditeit geëxtraheerd met speciale aandacht voor wondcomplicaties. Alle patiënten werden minimaal 12 maanden post-operatief uitgenodigd op de polikliniek voor lichamelijk onderzoek om een recidief littekenbreuk te kunnen opsporen. Bij 14 patiënten (26,4%) traden post-operatieve complicaties op. De onlay techniek gaf significant meer complicaties in vergelijking met de inlay en sublay techniek. Reherniatie trad bij 15 patiënten (28,3%) op. Het reherniatiepercentage na de inlay techniek was significant hoger ten opzichte van de sublay techniek (44% versus 12%,  $P = 0,03$ ). Alhoewel het reherniatiepercentage na de inlay techniek hoger was dan die na gebruik van de onlay techniek (44% versus 23%) was het verschil niet significant ( $P = 0,20$ ). Geconcludeerd werd dat de sublay techniek aantrekkelijker lijkt ten opzichte van de onlay en inlay.

Expanded-polytetrafluoroethyleen (e-PTFE) is een aantrekkelijk biomateriaal om grote buikwanddefecten mee te reconstrueren, zeker indien er geen interpositie van



peritoneum of omentum tussen patch en darmen mogelijk is. Het risico op seroomvorming en infectie van de patch zijn echter belangrijke nadelen, zoals beschreven in hoofdstuk 4. Om het risico op infectie te verkleinen is er een e-PTFE patch geïmpregneerd met zilverzouten en chloorhexidine ontwikkeld (Gore-Tex dual mesh plus with holes, W.L. Gore and associates Inc., Flagstaff, Arizona, USA) (e-PTFE DL-plus patch).

In **Hoofdstuk 7** wordt een experimentele studie beschreven om te bepalen of het impregneren van een e-PTFE patch met zilverzouten en chloorhexidine invloed heeft op de biocompatibiliteit, adhesievorming aan de patch en hernatie. In vitro werd de afgifte van zilverzouten van e-PTFE DL-plus patch in gedemineraliseerd water bepaald en het cytotoxische effect in fibroblast-celkweken bestudeerd. Binnen 24 uur traden er toxische  $Ag^+$  concentraties in het gedemineraliseerde water op. De fibroblast-celkweken lieten een zone van gedestrueerde fibroblasten zien rond de e-PTFE DL-plus patch en een significant lagere cel proliferatie in vergelijking met de controle e-PTFE patch zonder zilverzouten en chloorhexidine (e-PTFE DL patch).

Vervolgens werd in 30 Wistar ratten een buikwanddefect gecreëerd en gereconstrueerd met behulp van een e-PTFE DL-plus patch of een e-PTFE DL patch. De ratten werden geofferd na 2 maanden en obductie werd verricht om de inflammatoire respons, de ingroei van fibrocollageen weefsel in de patch, hernatie en mate van adhesie aan de patch te bepalen. In iedere groep overleed een rat in de eerste week na operatie tengevolge van hernatie en strangulatie van de darmen. Geen van de ratten ontwikkelde wondgenezingsstoornissen. Met behulp van de microscoop werd geen ingroei van fibrocollageen weefsel aangetoond in beide patches en aan beide zijden van de patch. In tegenstelling tot de niet-geïmpregneerde patch, liet de e-PTFE DL-plus patch massale infiltratie met granulocyten in het vetweefsel rond de patch zien en tevens necrose van dit vetweefsel. Er is een trend in de richting van een hoger hernatiepercentage in de e-PTFE DL-plus patch groep (80%) ten opzichte van de e-PTFE DL patch groep (53%) ( $P = 0.06$ ,  $X^2$ -test, enkelzijdig). De mediane adhesie score in de e-PTFE DL-plus patch (2, range 1-3) was vergelijkbaar met die in de e-PTFE DL patch (1, range 0-2). Geconcludeerd werd dat de impregnatie van de e-PTFE patch met zilverzouten en chloorhexidine leidt tot een verminderde biocompatibiliteit.

Het gebruik van een intraperitoneale polypropyleen mesh (PPM) om grote buikwanddefecten te reconstrueren gaat dikwijls gepaard met adhesievorming en schade aan de intra-abdominale organen. Polyglactin 910 mesh (PGM) is een resorbeerbare mesh, die vaak als barrière tussen PPM en de intra-abdominale organen wordt gebruikt.

In **Hoofdstuk 8** wordt een experimentele studie beschreven om te bepalen of de interpositie van PGM tussen PPM en de darmen invloed heeft op de biocompatibiliteit, hernatie en adhesievorming. In 80 ratten werd een 2 x 3 cm groot buikwanddefect gemaakt. De ratten werden willekeurig in 2 groepen van ieder 40 ratten verdeeld. In één groep werd het defect gereconstrueerd met behulp van een 2.5 x 3.5 cm grote PPM, in de andere groep met een 2.5 x 3.5 cm groot PPM met polyglactin mesh (PPM-PGM). Telkens werden 10 ratten per groep geofferd na 1, 2, 3 en 6 maanden, waarna obductie werd verricht om de mate van adhesievorming en het hernatiepercentage te bepalen. Biopsieën van de overgang tussen fascia en mesh werden afgenomen voor histologisch onderzoek. Er ging één rat uit de PPM groep vroegtijdig dood. Na 1, 2 en 3 maanden werd geen hernatie aangetoond in de ratten van de PPM groep. Na 6 maanden had één van de 9 PPM ratten een hernatie. Er gingen 2 ratten uit de PPM-PGM groep vroegtijdig dood. Twee ratten hadden een hernatie na 1 maand en 3 ratten na 6 maanden. De adhesie score, na 1, 2, 3 en 6 maanden, in de PPM groep (mediaan 3, spreiding 2-3) was niet verschillend van die in de PPM-PGM groep (mediaan 3, spreiding 2-3). Histologisch onderzoek liet een kapsel van fibrocollageen weefsel rond de polypropyleen vezels zien, dat rijpte bij langere implantatieduur. In beide groepen was er in de eerste maand een inflammatoire respons rond de prothese. De inflammatoire respons was heftiger rond de PPM-PGM. Er werd geconcludeerd dat de interpositie van PGM tussen PPM en de intra-abdominale organen geen invloed heeft op de vorming van adhesie of hernatie.

In **Hoofdstuk 9** worden verschillende anti-adhesieve en mechanische barrières ter preventie van adhesievorming van omentum of darmen aan PPM getest. In 60 Wistar ratten werd een 2 x 3 cm groot buikwanddefect gemaakt. De ratten werden willekeurig verdeeld in 6 groepen van 10 ratten. Het buikwanddefect werd gereconstrueerd met behulp van PPM (controle), PPM met auto-cross-linked polymeren (ACP) gel, PPM met fibrinogeen lijm (FG), polypropyleen/expanded-polytetrafluoroethyleen (e-PTFE) mesh, polypropyleen met natrium hyaluronate/carboxymethylcellulose coating (HA/CMC) mesh, of polypropyleen-collageen met polyethylene-glycol/glycerol coating (CPGG) mesh. De wonden werden de eerste twee weken na de reconstructie dagelijks gecontroleerd. Na twee maanden werden de ratten geofferd om de mate van adhesievorming, hernatie en treksterkte van de mesh-fascie overgang te bepalen. Zes ratten hadden een geïnfecteerde mesh; drie ratten uit de PPM/e-PTFE groep, 2 ratten uit de PPM/CPGG groep en een rat uit de PPM/APC groep. In de PPM/HA/CMC groep en de PPM/ACP groep was de adhesie score significant lager ten opzichte van de controle (PPM) groep. Het hernatiepercentage van de PPM/ACP groep was significant hoger ten opzichte van alle andere groepen. De gemiddelde treksterkte van de mesh-fascie overgang  $1.2 \text{ N/mm}^2$  (95% CI  $0.9\text{-}1.4 \text{ N/mm}^2$ ) in de PPM/HA/CMC groep was significant hoger dan die in alle andere groepen ( $P < 0.005$ ). Er werd geconcludeerd

dat PPM/HA/CMC het meest voldoet aan de ideale mesh, gezien de superieure anti-adhesieve eigenschappen, de goede verankering aan de fascie en het lage herniatiepercentage.

## discussie

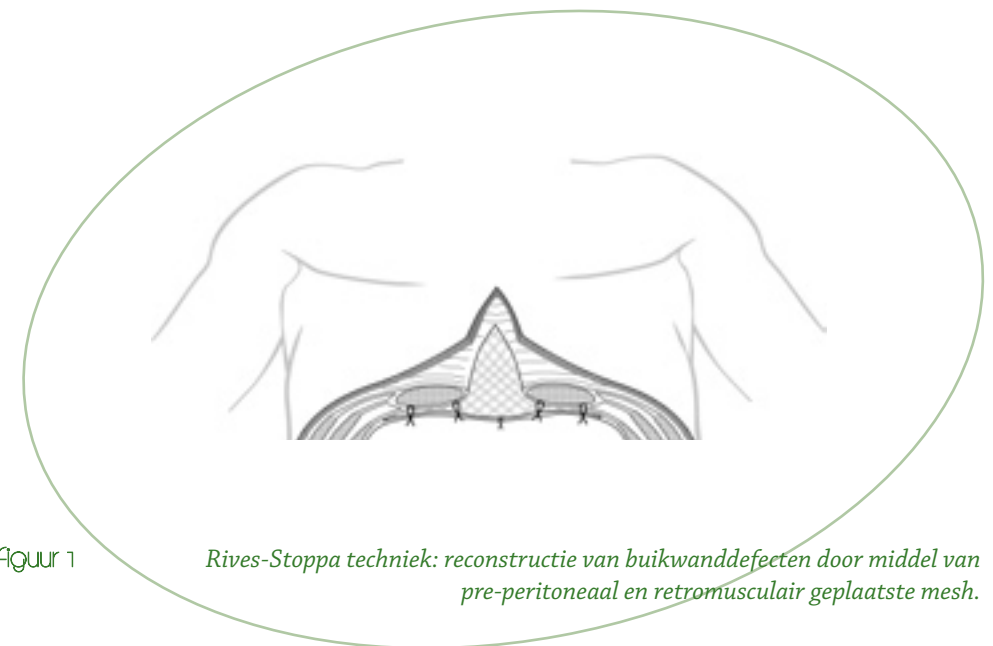
Reconstructie van grote littekenbreuken is nog steeds een uitdagend probleem voor chirurgen. Omdat bij grote littekenbreuken het fasciedefect niet primair kan worden gesloten, zal het fasciedefect moeten worden overbrugd met prothetisch of autoloog materiaal. Hiervoor zijn verschillende operatietechnieken beschikbaar. Reconstructie met autoloog materiaal is vooral aantrekkelijk bij gecontamineerde of geïnfecteerde buikwanddefecten. In **Hoofdstuk 3** worden de resultaten van de verschillende operatietechnieken voor reconstructie van een buikwanddefect met autoloog materiaal in de literatuur beschreven. De meeste studies gaan over de “componenten separatie techniek” (CST). CST is een aantrekkelijke, relatief eenvoudige operatietechniek; de post-operatieve morbiditeit en het (re)hernatiepercentage is echter hoog.

Seroomvorming en wondinfecties zijn de belangrijkste post-operatieve complicaties na CST.<sup>2,3</sup> Wondcomplicaties worden bij gemiddeld 24% van de patiënten gevonden; de in de literatuur gerapporteerde percentages variëren echter aanzienlijk.<sup>4</sup> Waarschijnlijk wordt in de meeste studies de incidentie van wondcomplicaties onderschat, omdat de meeste studies een retrospectieve opzet hebben en in slechts enkele de methode van wondcontrole wordt genoemd.<sup>4</sup> De uitgebreide dissectie en daardoor het grote subcutane wondoppervlak in combinatie met het klieven van de perforerende takken van de arteria epigastrica, die de vascularisatie van de voorste buikwand verzorgen, zijn waarschijnlijk belangrijke oorzakelijke factoren voor gestoorde wondgenezing. Bij het verrichten van de CST lieten Lowe et al. en Saulis et al. de perforerende arteriën rond de navel intact.<sup>5,6</sup> Zij claimen dat hierdoor huidnecrose voorkomen kan worden. Wij hebben deze techniek verder aangepast door ontwikkeling van een endoscopisch geassisteerde, minimaal invasieve CST, zoals beschreven in **Hoofdstuk 5**. Door toepassing van deze techniek wordt de subcutane dissectie beperkt en de vascularisatie van de huid gespaard. De eerste resultaten zijn veelbelovend, maar de ervaring met deze techniek is vooralsnog beperkt. Verscheidene Amerikaanse klinieken hebben de techniek overgenomen, maar hebben deze slechts bij weinig patiënten toegepast en tot op heden zijn er geen resultaten gepubliceerd. Er is behoefte aan goede grote series van opeenvolgende patiënten en een prospectief gerandomiseerde studie die de endoscopisch-geassisteerde CST vergelijkt met de originele techniek.

Het in de literatuur vermelde relatief hoge rehernatiepercentage van 18%, na een follow-up van tenminste 12 maanden, is een nadeel van de CST (**Hoofdstuk 3**). De methode van post-operatieve follow-up is echter in de meeste studies slecht gerapporteerd en dus in werkelijkheid waarschijnlijk hoger. Het rehernatiepercentage bij 43 patiënten, geopereerd in 5 Nederlandse ziekenhuizen was 32% na een periode van minimaal 12 maanden na operatie (**Hoofdstuk 2**). Al deze patiënten werden door hun eigen chirurg poliklinisch gecontroleerd. In een prospectief gerandomiseerde multicenter studie was het rehernatiepercentage zelfs 50% (**Hoofdstuk 4**). Dit is vergelijkbaar met het rehernatiepercentage na primair hechten van littekenbreuken.<sup>7,8,9</sup>

Waarschijnlijk kunnen de resultaten van een buikwandreconstructie worden verbeterd door het gebruik van biomaterialen om het defect te overbruggen of de fascie te versterken bij primair sluiten. Echter bij een prospectief gerandomiseerde multicenter studie bleken de resultaten van CST beter ten opzichte van reconstructie met prothetisch materiaal. Bij 7 van de 18 patiënten ging de prothese namelijk verloren door infectie van de prothese ten gevolge van seroomvorming, huidnecrose en wondinfecties (**Hoofdstuk 4**).

Indien het fasciedefect wordt overbrugd met prothetisch materiaal is dit alleen bedekt door huid en subcutis. Het risico op infectie van de prothese is dan hoog, zelfs bij de beperkte wondgenezingsstoornissen, die vaak bij deze patiënten optreden. De pre-peritoneale en retromusculaire positie van de prothese volgens Rives-Stoppa (Figuur 1) geeft betere resultaten.<sup>10</sup>



FIGUUR 1

*Rives-Stoppa techniek: reconstructie van buikwanddefecten door middel van pre-peritoneaal en retromusculair geplaatste mesh.*

Indien wondcomplicaties optreden bij kleine littekenbreuken, blijft de prothese bedekt met vitale spier of fascie waardoor infectie van de prothese kan worden voorkomen. Een recente prospectief gerandomiseerde multi-center studie, waarbij de Rives-Stoppa techniek werd verricht met zwaar versus lichtgewicht meshes, toonde een reherniatiepercentage van respectievelijk 7 en 17%.<sup>11</sup> Meerdere retrospectieve studies melden dezelfde resultaten na de Rives-Stoppa techniek voor buikwanddefect reconstructie.<sup>7-15</sup> Gebaseerd op deze studies en onze eigen ervaring met de pre-peritoneale en retro-musculaire mesh reconstructie lijkt het aannemelijk dat de combinatie van CST met de Rives-Stoppa techniek de resultaten verbetert ten opzichte van CST alleen. Door de combinatie van beide technieken worden de cosmetische en functionele voordelen van het herstel van de anatomie van de buikwand samen gebracht met de lagere reherniatie kans van de mesh reconstructie. In 2004 is er een prospectief gerandomiseerde multi-center studie (RAPP) trial gestart waarbij de originele CST vergeleken wordt met de gecombineerde CST/Rives-Stoppa reconstructie.

Er zijn verschillende soorten prothetische materialen ontwikkeld voor buikwandreconstructie. Het ideale prothetische materiaal zou tegenstrijdige eigenschappen moeten hebben. De prothese zou goed moeten verankeren aan de fascie door ingroei van fibrocollageen weefsel in de prothese, echter adhesies van intra-abdominale organen aan de prothese zouden voorkomen moeten worden. Polypropyleen mesh (PPM) wordt het meest gebruikt omdat het bij de meeste patiënten effectief is. PPM is echter minder geschikt voor reconstructie van (zeer) grote buikwanddefecten, omdat het peritoneum en/of het omentum voor interpositie tussen mesh en darmen meestal ontbreekt. De meerderheid van de chirurgen is terughoudend om PPM in direct contact met de darmen te plaatsen. In de laatste decennia zijn er prothetische materialen ontwikkeld die in direct contact met de darmen geplaatst kunnen worden. Eén van deze materialen is expanded-polytetrafluoroethyleen (e-PTFE). Bij reconstructies met een intra-abdominale prothese wordt e-PTFE patch daarom vaak als alternatief voor PPM gebruikt. E-PTFE is een zacht, plooibaar en sterk hydrofoob prothetisch materiaal. De microporeuze zijde voorkomt ingroei van fibrocollageen weefsel, hetgeen resulteert in significant minder adhesies ten opzichte van PPM.<sup>16</sup> Echter door onvoldoende verankering ten gevolge van het gebrek aan ingroei van fibrocollageen weefsel, is er in (pre-)klinische studies sprake van een hoog rehernatiepercentage.<sup>16,17</sup> In retrospectieve studies varieert het rehernatiepercentage tussen de 0 en 50%.<sup>3,18-27</sup> Door het hydrofobe karakter van de prothese is deze verder gevoelig voor infecties.<sup>28</sup> Infectie van de prothese, waardoor resectie van de prothese noodzakelijk is, komt in klinische studies voor bij 2 tot 38% van de patiënten.<sup>3,18-30</sup> Om het risico op infectie van de e-PTFE patch te verminderen is deze geïmpregneerd met zilverzouten en chloorhexidine (Gore-Tex dual mesh plus with holes, W.L. Gore and associates Inc., Flagstaff, Arizona, USA). Deze patch werd gebruikt in een prospectief gerandomiseerde multi-

center studie waarbij hij werd vergeleken met CST. Zoals al eerder genoemd leidde dit bij 7 van de 18 patiënten tot een geïnfecteerde patch ten gevolge van wondcomplicaties waaronder huidnecrose en seroomvorming (**Hoofdstuk 4**). In een experimentele studie werd aangetoond dat de geïmpregneerde e-PTFE patch minder biocompatibel is dan de niet-geïmpregneerde e-PTFE patch (**Hoofdstuk 7**). Hoewel de e-PTFE patch bruikbaar is bij laparoscopisch littekenbreukherstel,<sup>31</sup> is de patch derhalve minder geschikt voor reconstructie van grote littekenbreuken.

De reconstructie van buikwanddefecten met zwaargewicht PPM verandert de fysische eigenschappen van de buikwand hetgeen kan resulteren in stijfheid en pijnklachten.<sup>32-34</sup> Er zijn modificaties van deze originele zwaargewicht PPM ontwikkeld om de hoeveelheid polypropyleen die geïmplanteerd wordt te verminderen. In een recente gerandomiseerde klinische studie leidde de Rives-Stoppa reconstructie met lichtgewicht PPM tot een toegenomen recidiefpercentage; het verschil was echter niet significant.<sup>11</sup>

Indien PPM in contact komt met de darmen blijft adhesievorming een serieus probleem, zeker als de patiënt opnieuw geopereerd moet worden.<sup>35</sup> De meest eenvoudige manier om de darmen te beschermen tegen PPM is door interpositie van een resorbeerbare polyglactin 910 mesh (PGM). Echter, in een experimentele studie in ratten werd aangetoond dat PGM de adhesievorming niet voorkomt (**Hoofdstuk 8**). In experimentele studies waarbij een lichtgewicht mesh bestaand uit polypropyleen gecombineerd met polyglactin (Vypro mesh, Ethicon, Johnson & Johnson Medical, Norderstedt, Germany) en een lichtgewicht mesh bestaande uit polypropyleen gecombineerd met polydioxanon gecoat met geoxideerde cellulose (Proceed mesh, Ethicon, Johnson & Johnson Medical, Norderstedt, Germany) werden getest, leverde dezelfde resultaten op.<sup>36-40</sup>

De recent ontwikkelde prothetische materialen zijn gebaseerd op mechanische interpositie of hebben chemische anti-adhesiva om adhesievorming van darmen aan de PPM te voorkomen. In twee recent uitgevoerde experimentele studies bleek polypropyleen mesh met carboxymethylcellulose-natrium hyaluronaat coating (Sepramesh, Genzyme Corporation, Cambridge, USA) superieur ten opzichte van polypropyleen met collageen/polyethyleen-glycol/glycerol coating (Parietene Composite mesh, Sofradim International, Trévoux, France) en polypropyleen met e-PTFE coating (Bard Composix mesh, Bard, New Jersey, USA), ten aanzien van adhesiepreventie. Polyester met collageen/polyethyleen-glycol/glycerol coating (Parietex Composite mesh, Sofradim International, Trévoux, France) gaf vergelijkbare resultaten ten opzichte van Pa-

riete Composite mesh.<sup>39-42</sup> Er ontbreken echter klinische studies over de resultaten van de verschillende soorten PPM met anti-adhesieve modificaties. Hiervoor zouden gerandomiseerde studies verricht moeten worden.

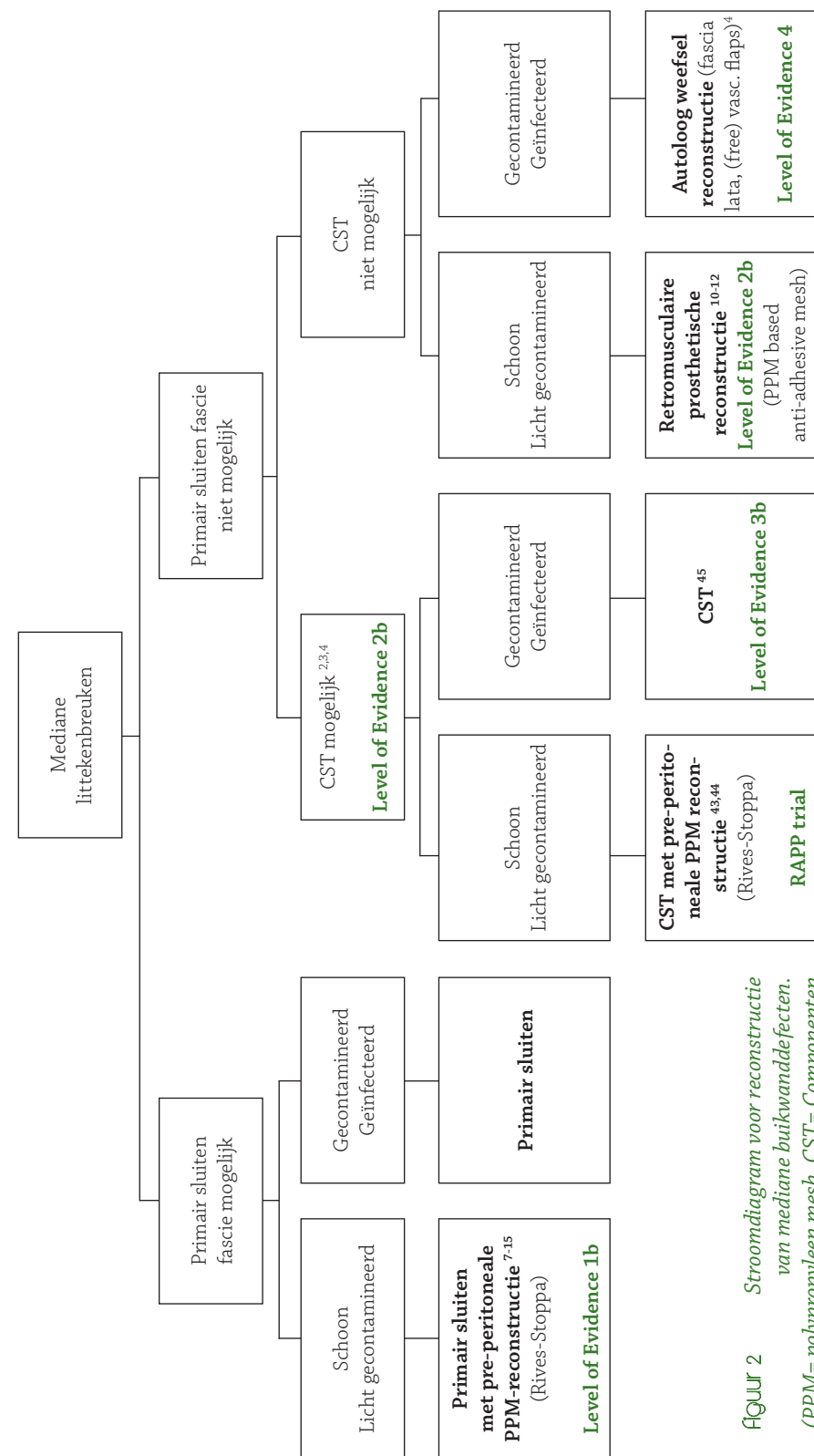
## aanbevelingen

Reconstructie van grote mediane buikwanddefecten is grotendeels gebaseerd op studies met een lage “level of evidence” of “expert opinion”. Verschillende operatie-technieken worden bepleit, maar prospectieve en gerandomiseerde studies zijn schaars. Voor reconstructie onder schone of licht gecontamineerde omstandigheden geeft mesh reconstructie veel betere resultaten dan primair sluiten van de fascie met hechtingen (level of evidence 1b).<sup>7-15</sup> Pre-peritoneale en retromusculaire positie van de mesh heeft de voorkeur boven implantatie als inlay of onlay mesh (level of evidence 3b).<sup>15,35,43-54</sup> De keuze van de mesh wordt voornamelijk gebaseerd op experimentele data. Klinische studies over het gedrag van de mesh op lange termijn ontbreken grotendeels. Er is nauwelijks informatie beschikbaar over reconstructie met een mesh in gecontamineerd of geïnfecteerd milieu. Over het algemeen zouden biomaterialen in deze omstandigheden niet gebruikt moeten worden in verband met het risico op chronische infectie van de mesh of afstoten van de mesh. Primair sluiten met hechtingen of een CST zijn onder deze omstandigheden het meest raadzaam, ondanks het hoge recidiefpercentage.

Gebaseerd op de studies in dit proefschrift en de beschikbare literatuur is een algoritme voor de reconstructie van grote mediane buikwanddefecten gemaakt (Figuur 2). De keuze voor een bepaalde techniek wordt voornamelijk bepaald door twee factoren. Ten eerste, of de fascie primair te sluiten is en ten tweede de mate van contaminatie van de buikwand.

Indien primair sluiten van de fascie mogelijk is, valt onder schone of licht gecontamineerde omstandigheden een pre-peritoneale en retromusculaire gepositioneerde PPM (Rives-Stoppa) aan te bevelen.<sup>7-15,43</sup> Omdat er geen goede gegevens beschikbaar zijn over de resultaten van mesh reconstructie in gecontamineerd of geïnfecteerd milieu wordt dit afgeraden. Derhalve wordt primair sluiten met hechtingen geadviseerd in gecontamineerd of geïnfecteerd milieu, waarbij het reherniatiepercentage tot 50% geaccepteerd moet worden.<sup>7-9,43</sup>

Indien primair sluiten van de fascie niet mogelijk is, is CST de aanbevolen behandeling om het fasciedefect te sluiten (level of evidence 2b).<sup>2,3,4</sup> Waarschijnlijk zal een



**FIGUUR 2** Stroomdiagram voor reconstructie van mediane buikwanddefecten. (PPM= polypropyleen mesh, CST= Componenten Separatie Techniek)



combinatie van CST met een pre-peritoneale en retromusculaire mesh het beste resultaat geven. Deze combinatie wordt al gesuggereerd door Dibello en Lowe, die deze combinatie bij een deel van hun patiënten hebben toegepast.<sup>55,56</sup> De resultaten van de prospectief gerandomiseerde multi-center studie (RAPP-trial) die CST vergelijkt met CST plus pre-peritoneale en retromusculaire mesh zal antwoord geven op deze vraag. In gecontamineerd of geïnfecteerd milieu wordt de originele CST geadviseerd om dezelfde reden als al eerder genoemd (level of evidence 3b).<sup>57</sup> Is een CST technisch gezien niet mogelijk, dan blijft mesh-reconstructie de aanbevolen methode, indien de mesh bedekt kan worden met huid van volledige dikte (level of evidence 2b).<sup>10-</sup>  
<sup>12</sup> Deze mesh moet dan pre-peritoneaal en retromusculair gepositioneerd worden met voldoende overlap van de fascia. Indien mesh-reconstructie gecontraïndiceerd is, wordt reconstructie met fascia lata graft, vrij of gesteelde tensor fasciae latae flap geadviseerd (level of evidence 4-5).<sup>4</sup> De combinatie van mesh bedekt met een gesteelde omentum flap (omental sandwich techniek) is onder deze omstandigheden een aantrekkelijk alternatief.<sup>58</sup>

Indien het peritoneum niet tussen de darmen en de mesh gesloten kan worden zal een intra-peritoneale en retromusculaire reconstructie noodzakelijk zijn. De keuze voor het type mesh voor deze reconstructie kan alleen gebaseerd worden op klinische studies met een “intermediate” tot “low level of evidence” of op experimentele studies. Een e-PTFE patch is gecontraïndiceerd in verband met de hoge kans op infectie van de patch (level of evidence 2b), ondanks het feit dat de reherniatie niet verschilt van reconstructies met PPM (level of evidence 3b).<sup>3,18-30</sup> De meeste studies gaan over zwaargewicht polypropyleen mesh (PPM). De verankering aan de aanliggende fascia is goed, maar adhesievorming is een belangrijk nadeel. Daarom is PPM niet geschikt om direct in contact te komen met de darmen.<sup>35</sup> In experimentele studies is aangetoond dat de modificaties van PPM met chemische anti-adhesieve eigenschappen zoals cellulose, hyaluronaat of glycerol coating betere resultaten geven ten opzichte van de modificaties met een mechanische barrière zoals polyglactin mesh of e-PTFE. Voor de intra-abdominale en retromusculaire buikwandreconstructie zou een van deze op polypropyleen-gebaseerde meshes met chemische anti-adhesieve eigenschappen (Proceed mesh, Sepramesh of Parietene composite mesh) gebruikt moeten worden, ondanks het ontbreken van klinische studies.<sup>39-42</sup>

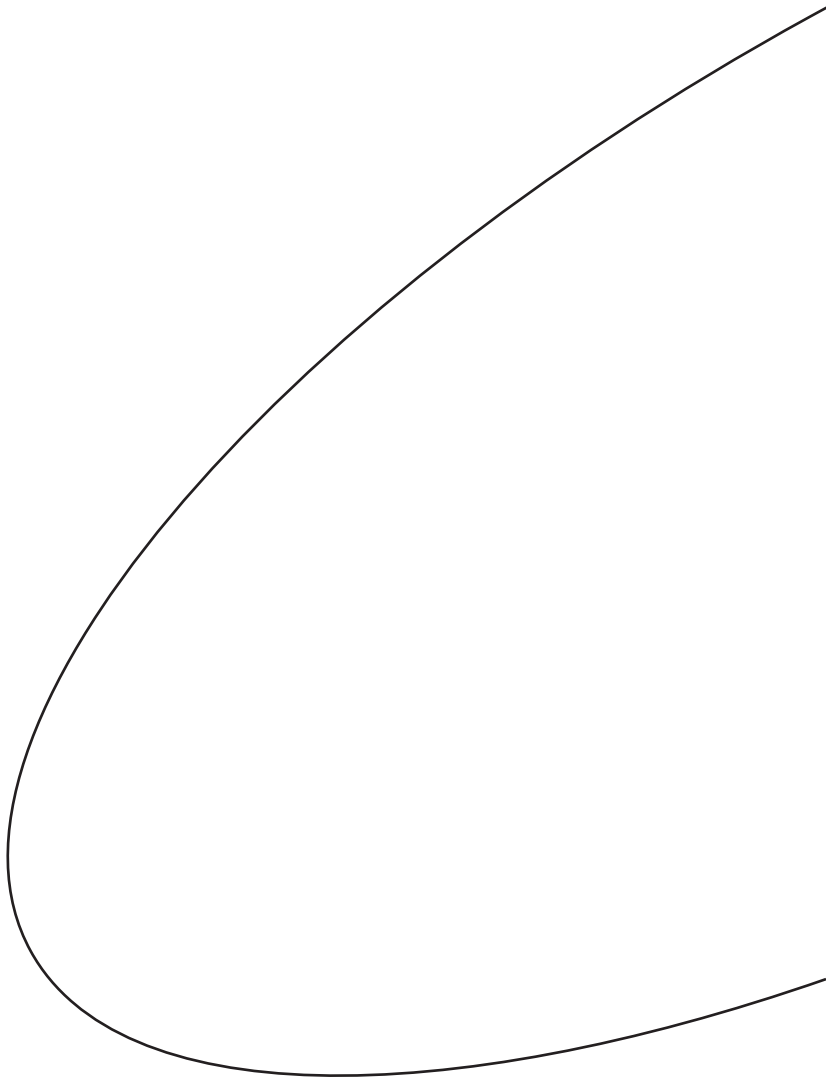
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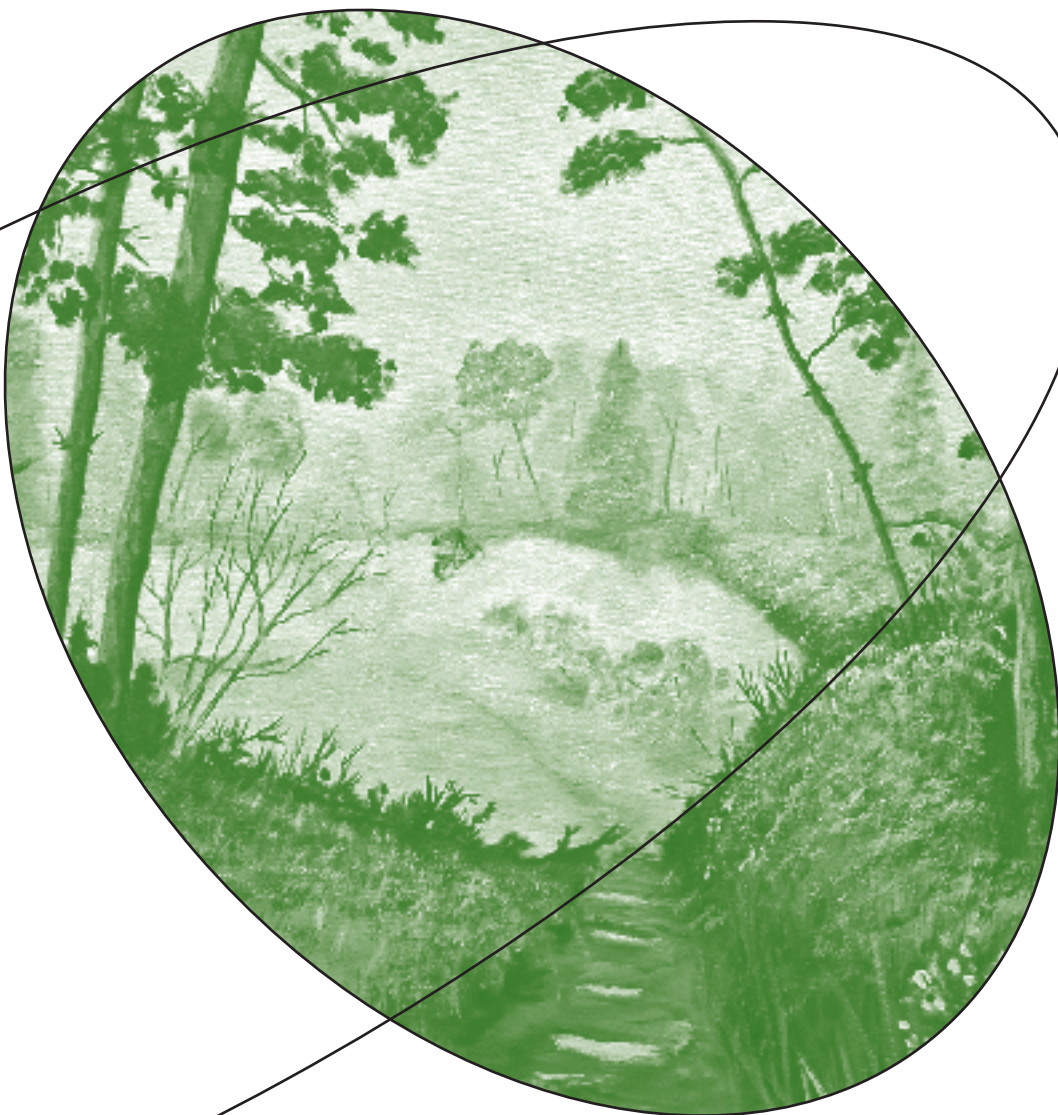
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Damage due to a Kirschner wire.

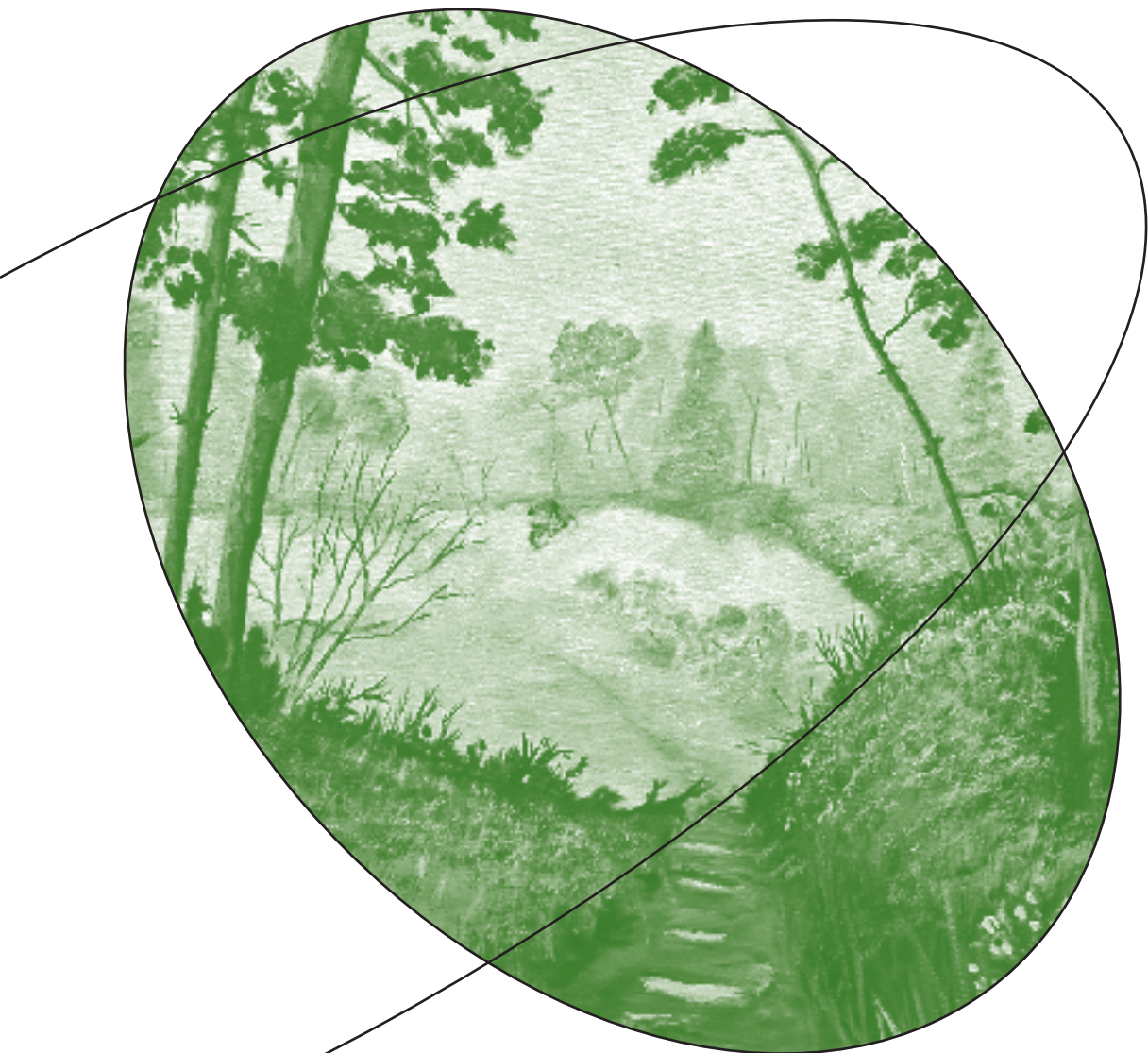
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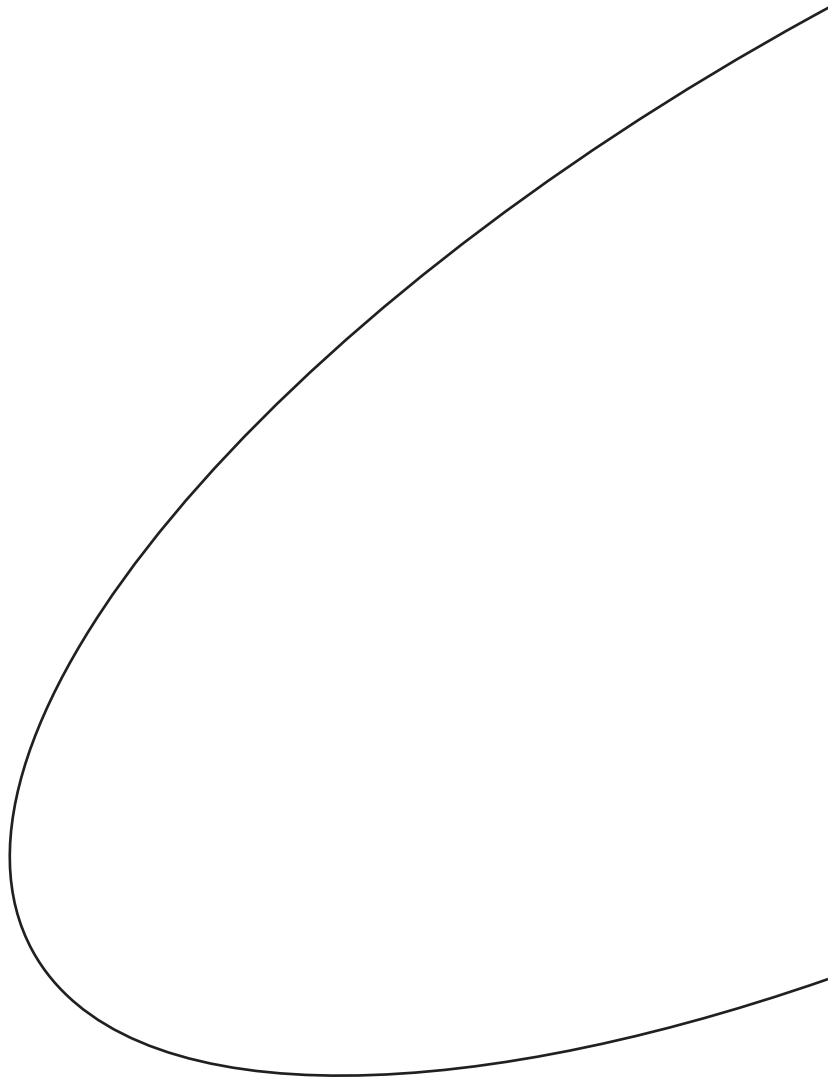
Collega’s Canisius-Wilhelmina Ziekenhuis en UMC Sint Radboud. Dank voor de prettige werksfeer en de collegialiteit.

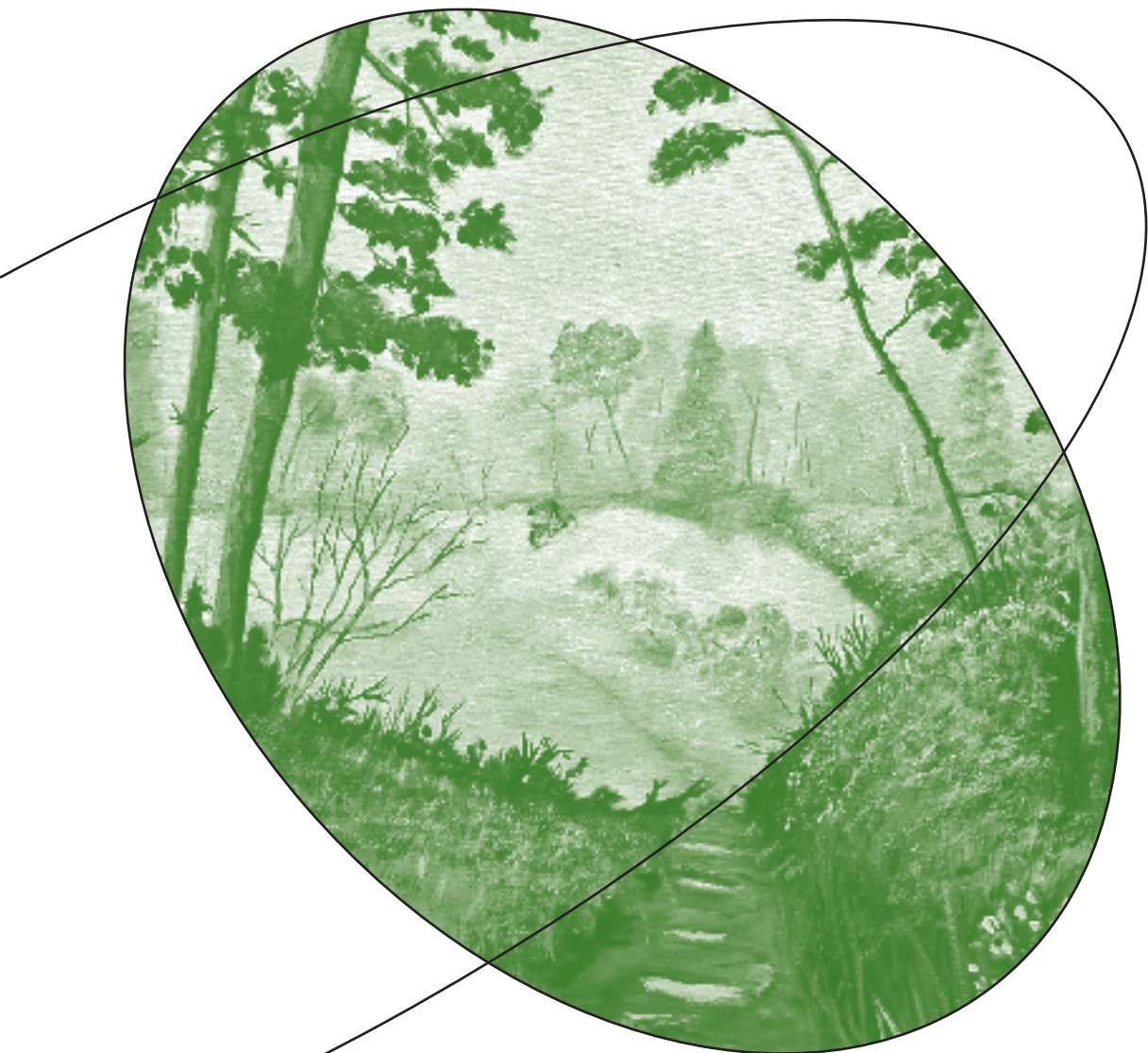
Lieve ouders en schoonouders, dank voor jullie onvoorwaardelijke steun, vertrouwen en bijstand.

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curriculum vitae

Tammo de Vries Reilingh werd geboren op 8 december 1971 in Laren (Noord-Holland). In 1992 behaalde hij het VWO-diploma aan het Chr. College Nassau Veluwe te Harderwijk. Aansluitend begon hij de studie geneeskunde aan de Vrije Universiteit te Amsterdam en behaalde hij zijn doctoraal examen in 1997. Tijdens het volgen van de co-schappen startte het onderzoek naar grote buikwanddefecten onder leiding van Prof.dr. R.P. Bleichrodt. Hij behaalde zijn arts-examen in 1999. Daarna werkte hij als arts-onderzoeker en AGNIO Heelkunde aan het VUMC te Amsterdam. In december 2000 verhuisde hij naar Nijmegen, als AGNIO Heelkunde aan het UMC Sint Radboud, om zijn onderzoek te kunnen voortzetten.

In mei 2002 startte hij met de opleiding tot chirurg in het Canisius-Wilhemina Ziekenhuis te Nijmegen (opleider: dr. E.D.M. Bruggink en later dr. W.B. Barendregt). In mei 2005 keerde hij terug naar het UMC Sint Radboud voor het vervolg van de opleiding (opleider: Prof.dr. R.P. Bleichrodt). Sinds mei 2007 voltooit hij zijn opleiding tot chirurg met het differentiatie jaar abdominale chirurgie wederom in het Canisius-Wilhelmina Ziekenhuis.

Hij is actief als arts tijdens wielervedstrijden en maakt dan deel uit van het team van Stichting Service Médical; zo kan hij zijn vak combineren met zijn grote passie.

Tammo de Vries Reilingh is getrouwd met Elly en samen hebben ze twee zonen Paul en Tijn. In juli 2007 verwachten zij hun derde kind.

